Exhibits cited in Gilson et al., Claffey, O'Shaughnessy, and Roubin Declarations

EXHIBIT	DESCRIPTION
1	"NEUROGUARD DETAILS & DIMS" PAGE FROM LAB NOTEBOOK. 7 - DAVID VALE
2	REVIEW OF POLYIMIDE TUBING FUNCTIONALITY
3	DESIGN REVIEW MINUTES
5	MEMO REGARDING NEUROSCREEN PACKAGING
7	LAKE REGION INVOICE # 1560 WITH COVER FAX
8	PROJECT TEAM MEETING REVIEWS 02/25/98
9	EXPERIMENT INSTRUCTIONS FOR SOLUBLE CORE ASSEMBLY
10	EXPERIMENT INSTRUCTIONS FOR RETRIEVAL TIP INTEGRITY
11	INVOICE FROM UPS OF IRELAND
12	INVOICE RE MACHINED PERSPEX ROD
13	INVOICE OF ORDERS PLACED 02/11/98 ; 02/18/98 ; 02/23/98
14	INVOICE FOR LASER - CUT PARTS FROM NITINOL TUBING (SLIT TUBE) ACCORDING DRAWING CE 97 003, REV. 04
15	PURCHASE ORDER FOR CLOSED COIL STAINLESS STEEL SPRING AS PER SPEC: CD97002 REV. 0
16	FAX RE PO 7510 FOR SPLINE PRESS TOOL
17	PURCHASE ORDER FOR ANNEALING OF MONEL 400 WIRE AND INVOICE FOR SAME
18	INVOICE FOR HEMOSTASIS Y - CONNECTOR
19	VALIDATION SCREENING PROTOCOL FOR SHRINKAGE OF PFTE ONTO COPPER MANDREL FOR THE FORMATION OF THE LOADING MECHANISM
20	PURCHASE ORDER FOR CLOSED COIL STAINLESS STEEL SPRING AND INVOICE FROM ASHFIELD SPRINGS FOR ORDER
21	PURCHASE ORDER FOR ANNEALING OF MONEL 400 WIRE AND INVOICE FOR SAME
22	PROJECT TEAM MEETING REVIEWS
23	DESCRIPTION OF TEMPLATE FOR GUIDE CATHETER ENTITLED " MANOEUVRABILITY FIXTURE "
24	DESCRIPTION OF A PROCEDURE TO OUTLINE A METHOD FOR DETERMINING THE MANOEUVRABILITY CHARACTERISTICS OF CATHETERS
25	DESCRIPTION OF METHOD FOR CALIBRATION OF FLOW METERS ON THE CIRCULATORY RIG
26	DRAWING OF FLOW METER / FLOW SENSOR PLACEMENT ON CAROTID ARTERY
27	DRAWING
28	DESCRIPTION / SPECIFICATION OF RETRIEVAL CATHETER
29	PURCHASE ORDER FOR RETRIEVAL CATHETER ASSEMBLY AS PER SPEC. SA 97006 REV.02 EXCEPT TAPERED LEG TIPS TO BE RO. 15
30	DRAWING OF CATHETER SHAFT
31	FAX RE DIRECTION TO MONTEFIORE
32	DESCRIPTION / SPECIFICATION FOR SOLUBLE CORE
33	PROJECT TEAM MEETING REVIEWS

34	LOADING MECHANISM SUB-ASSEMBLY DRAWING
35	PURCHASE ORDER FOR CONNECTOR AS PER MEDNOVA SPEC CC97012 REV 0 AND QOSINA INVOICE OF SAME
36	PURCHASE ORDER FOR CONNECTOR AS PER MEDNOVA SPEC CC97012 REV 0 AND QOSINA INVOICE OF SAME
37	SUMMARY OF MARCH 14, 1998 FIRST IN VITRO PLAQUE FILTRATION TEST
38	DESIGN REVIEW MINUTES
39	MEMO RE SCREENING VALIDATIONS
40	INVOICE FOR MACHINED PERSPEX ROD DRG. CA97-001 MODIFIED
41	LASER MACHINED COATED CORE
42	PURCHASE ORDER FOR LASER MACHINED COATED CORE
43	INVOICE FROM SPECTRALYTICS FOR SAME
44	LASER MACHINED COATED CORE - CHANGE REQUEST FORM
45	LASER MACHINED COATED CORE
46	PURCHASE ORDER
47	ADVICE NOTE
48	PROJECT TEAM MEETING
49	PURCHASE ORDER 7551
50	FAX SHEET REGARDING 5 DIFFERENT SPRINGS QUOTED ON REF. NO. 980533
51	PURCHASE ORDER -QOSINA
52	LOADING MECHANISM BONDING / LUBRICATING
53	DESCRIPTION OF 6MM SOLUBLE CORE (3)
54	DESCRIPTION OF 5MM SOLUBLE CORE (6)
55	"FILTER ELEMENT SA ROUTING" , STEPS OF CONSTRUCTION + DRAWING
56	PURCHASE ORDER + INVOICES FOR HEAT SHRINK PTFE TUBING
57	FAX RE QUOTE FOR PRODUCT
58	LAB NOTEBOOK. 7 - DAVID VALE - FILTER CATHETER
59	LAB NOTEBOOK. 7 - DAVID VALE - FILTER & DELIVERY CAT. REDESIGN
60	FAX RE NEUROSHIELD DESIGN CHANGES WITH DRAWINGS
61	PURCHASE ORDER FOR CLOSED COIL STAINLESS STEEL TENSION SPRING
62	INVOICE FOR CLOSED COIL STAINLESS STEEL TENSION SPRING
63	FAX RE 0.013" / 0.016" GUIDEWIRE WITH DRAWINGS
64	POLYIMIDE TUBING SAMPLE ORDER
65	EMAIL RE NEUROSHIELD SKETCHES
66	DRAWING OF FILTER
67	PURCHASE ORDER FOR LASER MACHINED COATED CORE AS PER SA 98003 REV. 03
68	INVOICE + PACKING LIST FROM SPECTRALYTICS FOR LASER MACHINED COATED CORE AS PER SA 98003 REV. 03
69	LETTER RE 01/28/98 MEETING + PROCESS IMPROVEMENTS
70	PURCHASE ORDER FOR RADIO FREQUENCY WELDING UNIT FOR MEDNOVA RETRIEVAL CATHETER TIP + INVOICE FROM ADAM SPENCE FOR SAME
71	QA INSPECTION RECORD OF CATHETER + INTRODUCER FROM ADAM SPENCE
72	QA INSPECTION RECORD OF CATHETER + INTRODUCER FROM ADAM SPENCE

73	INVOICE FOR 03/03/98 ; 03/04/98 ; 03/09/98 ; AND 03/10/98 ORDERS
74	DESIGN ACTIVITIES TABLE WITH SUBHEADINGS " DELIVERY CATHETER " , " FILTER CATHETER " , + " PACKAGE "
75	DRAWING OF STEPPED GUIDEWIRE
77	UPDATE ON TAKAO OHKI MODEL PRODUCT
78	FAX RE SPEC FOR STEPPED GUIDEWIRE
79	MONTEFIORE HOSPITAL, BRONX NY , 2ND IN VITRO PLAQUE FILTRATION TEST ; REF. OHKI MODEL
81	MEMO RE OKHI MODEL TRIAL ON 03/05/98 WITH DRAWING OF NEUROSHIELD DEVICE ASSEMBLED FOR THE TRIAL
82	LAB NOTEBOOK 12 - PADRAIG MAHER
83	EMAIL RE DESIGN OF NEUROSHIELD
84	FAX RE NITINOL TUBING
85	QA INSPECTION RECORD FOR RETRIEVAL CATHETER RE SPEC SA97006 + INVOICE FROM ADAM SPENCE FOR RETRIEVAL CATHETER
86	FAX RE HYPO TUBE
87	INVOICE FOR CUSTOMER ORDER 7551 - ASHFIELD SPRINGS
88	MEMO RE: GUIDEWIRE DIMENSIONS
90	PHOTO -JANUARY 98 NEUROGUARD - SUPPORT WIRE
91	IMAGES
92	CHAS TAYLOR EXPENSE REPORT MARCH 1998
93	PAUL GILSON EXPENSE REPORT APRIL 1, 1998
94	PAUL GILSON EXPENSE REPORT APRIL 2, 1998
95	PAUL GILSON EXPENSE REPORT MARCH 1998
96	INVOICE FROM DAWNLAUGH LTD. DATED 02/28/98
97	INVOICE FROM BOSTON SCIENTIFIC DATED 02/26/98
98	FAX WITH DRAWING OF GUIDEWIRE
99	SLIDE TITLED "CAROTID PTA GUIDEWIRE"
100	EMAIL RE MAIRSIL & RETURN TO WORK
101	PHOTO - CONTOUR BOTTLES
102	DIARY ENTRY - JULY 28, 1997
103	DIARY ENTRY - SEPTEMBER 8, 1997
104	DIARY ENTRY - DECEMBER 11, 1997
105	DIARY ENTRY - JANUARY 15, 1998
106	DIARY ENTRY - MARCH 14, 1998
107	DIARY ENTRY - MARCH 25, 1998
108	DIARY ENTRY - MARCH 26, 1998
109	DIARY ENTRY - APRIL 4 & 5, 1998

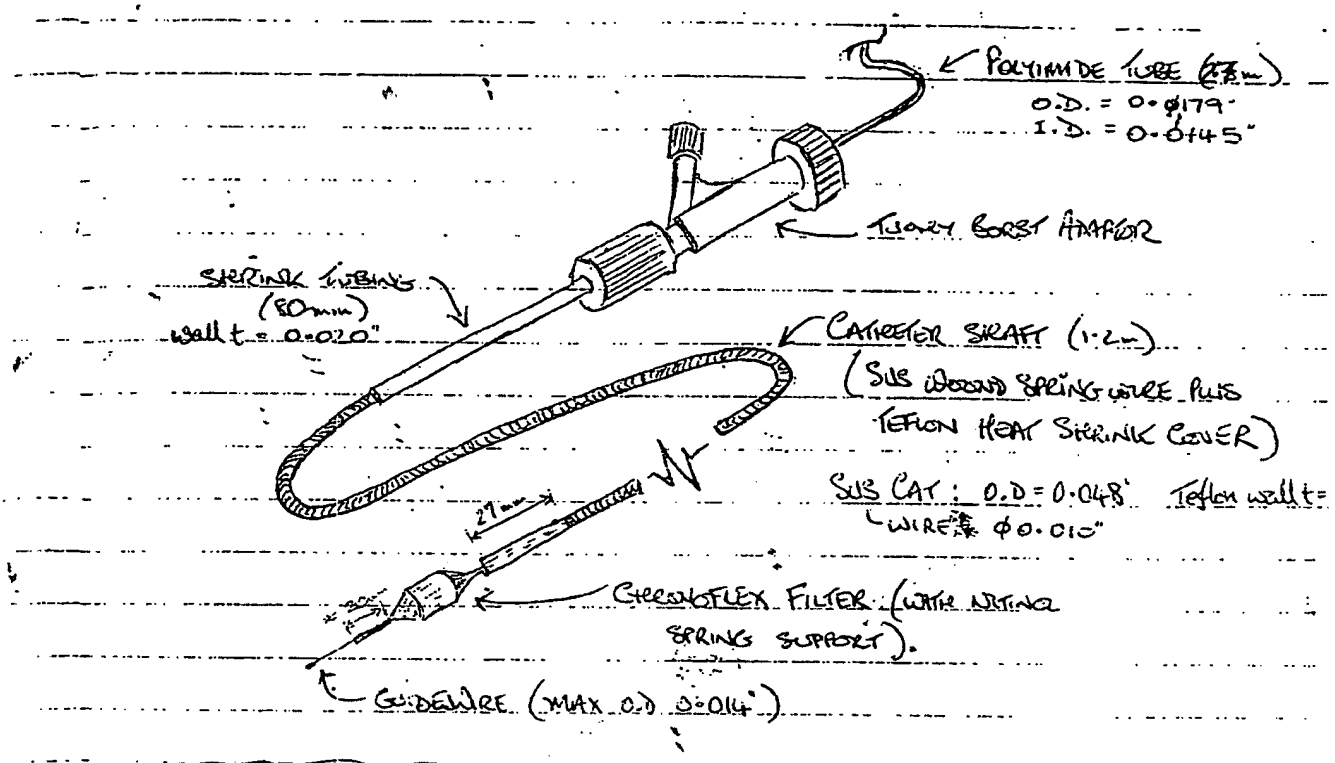
REDACTED

Witnessed by
E. Brady

REDACTED

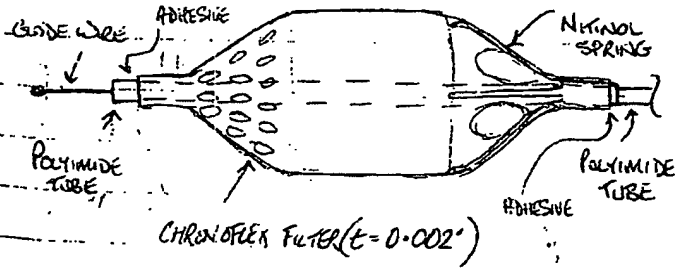
REDACTED

NEUROGUARD DETAILS + DIMS

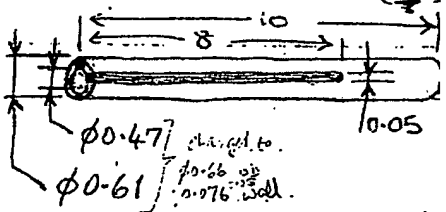


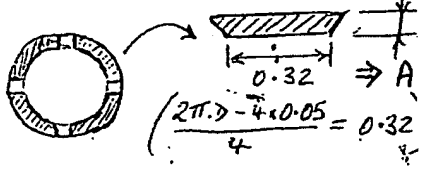
EQUIPMENT INTERFACE SPECS:	GUIDE WIRE	0.014"	max O.D.
	BALLOON CATHETER	0.020"	MIN LUMEN I.D.
	STENT BALLOON CATH.	"	"
	GUIDE CATHETER	0.100"	MIN LUMEN I.D.

CHRONOFLEX BALLOON FILTER:



NITINOL SPRING: (mm)





DIMENSIONS!

0.001" = 0.0254 mm

FRENCH = Circumference in mm

1 mm = 0.0394"

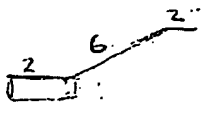


Exhibit 1.

REDACTED

Paul Gilson

From: PMaher [PMaher at mednova]
Sent: REDACTED
To: EBrady; FFarrell; JOShaughnessy; MClaffey; SEighan; RHoulihan
Subject: Review of Polyimide tubing functionality

To: file

On REDACTED, it was found that there was great difficulty in loading the 0.014" guide wire into the lumen of the 3m long Polyimide tubing. The diameter of the guide wire was measured at 0.0132" and the nominal dimension for the tubing is 0.0145" +/- 0.0002". The guide wire itself was in poor condition which did not aid matters but it was decided that the lumen was too tight over the 3m length and this lead to a gradual build up of interference between the guide wire and the polyimide tubing.

The following suggestions were put forward to aleviate the problem:

(1) Increase lumen ID but maintain the OD specification.
Samples will have to be obtained and tested in-house to determine if the strength of the polyimide is compromised.

(2) Use a low viscosity silicone fluid to pre-prep the lumen. This would lubricate the lumen which would make it easier for the guide wire to travel in the lumen.

(3) The lumen of the polyimide could be coated with a low friction material or hydrophilic coating.

(4) Change the material that is used to make the tubing. (ie. change from polyimide to a material with a lower coefficient of friction.)

(5) Review the cartoid procedure and shorten the tubing as much as possible.

(6) Devise mechanism for locking the polyimide tubing to the guide wire.

Clean 3m guide wires have been requested and changes to the polyimide tubing specifications are being sent to MicroLumen to obtain samples as soon as possible. Also, a polyimide tubing specification compatible with 0.021" balloon and stent systems is being drafted and sent to MicroLumen.

Padraig.

Exhibit 2

REDACTED

Paul Gilson

From: EBrady [EBrady at mednova]
Sent: REDACTED
To: MClaffey; SEighan; PMaher; JOShaughnessy; DVale
Subject: Design Review Minutes

To: Chas Taylor
To: Steven Horan

A conference call design review was held on REDACTED to discuss a number of key outstanding design issues and to attempt to agree the best direction to bring the design. In attendance were J O' Shaughnessy, Chas Taylor, Padraig Maher, David Vale and Eamon Brady. The main points of this meeting are as follows:

1. As it stands the push and flex characteristics of the device appear to be very good. An area we need to consider is the transitions between the 0.014" wire and the polyimide and more particularily the transition between the 0.018" polyimide and the catheter pod. The possibility of incorporating a transition in this region was discussed and may have merit. This transition section would act as a conically shaped cap to the catheter.

2. From discussions with clinitians in the field Chas felt that emboli were more likely to be showers of small emboli rather than large emboli. The 2mm holes in the proximal end of the device are appropriately sized for the procedure. The optimum size for the distal holes is not yet known as the size of emboli that we need to capture is largely unknown. However our current best guess is a reasonable starting point. Chas suggested that we may be able to evaluate the correct size of the holes more closely through employing a model which he is familiar with in New York.

3. The product will be commercialised in 4mm, 5mm and 6mm sizes.

4. Chas felt that thrombus formation on the balloon was unlikely to be a big issue as most patients are heperanised and antiplatelet agents are commonly employed. Furthermore, the balloon material is the same as is used in intra aortic balloons and there is no issue with these.

5. The product needs to be designed to deal with the following minimum and maximum pressure and flow rate conditions:

	Min	Max
Pressure	50 mmHg	200 mmHg
Flow Rate	0 litres	1 litre

6. The design of the retrieval catheter was discussed in detail. The OD of the retrieval cath should be as big as can get through a 9F guiding cath. It needs to be designed such that it is maintained concentric to the wire while being delivered over the lesion and stent area. The tip of the retrieval catheter needs to be transitioned such that it does not cause any hang up issues. The possibility of using a goose neck snare to retrieve the device was discussed. This approach has obvious merit in that it reduces the integrity requirements of the device.Chas will try to get a snare so as to evaluate this approach. The retrieval catheter should also have a Y connector.It was also agreed that the retrieval cath should have good flex and track at the distal tip.

7. There was no apparant advantage in using a double sterile barrier. It was agreed that the existing approach of a tray and a single barrier pouch is the way to go.

8. The package was considered to be very important to the success of the product. A retainer tube for the package was considered to be the best approach to retaining the polyimide tubing.

9. The meeting discussed wire movement in detail. It is felt by the R&D group that increasing the ID of the polyimide from 0.0145" to 0.0155" will significantly improve wire movement. However this may compromise integrity. Chas

Exhibit 3

felt that he would prefer to compromise on wire diameter than on polyimide OD and thus balloon ID. Changing the wire OD however has significant implications. Chas suggested the use of a wire with a proximal diameter of 0.012" and a distal end of 0.014" or 0.018". We would have to specifically develop this wire. This item will be discussed in more detail next week. In the mean time the strategy will remain unchanged.

10. Chas will try and source a side mounted pin vice.

REDACTED

Memorandum.

To: David Vale, Paul Gilson, Eamon Brady
Copy: John O'Shaughnessy
From: Chas Taylor
Subject: NeuroScreen Packaging
Date: REDACTED

MedNova

I had the opportunity to review the packaging layout with Peter Gaines comments as follows:

In principle the packaging layout is excellent. The size of the package is suitable for preparation on the scrub table or on the patient's legs prior to the procedure. The overall size of the box is OK for storage in the Cath Lab. The layout is markedly preferable to a single long package as we have previously discussed. Specific points regarding the packaging layout are as follows:

i) Location of the syringe and cannulae is excellent. Peter asked if the cannulae be pre-loaded onto the syringe to save this step during the procedure. I mentioned that it was probably best to have them separate as it was easier to fill the syringe if the cannulae was not already attached. He agreed with this.
ii) Tuohy-Borst Y connector. Peter agreed that there would be a syringe available on the sterile table to flush this device. He would like to have a three-way tap attached to the Y connector of the device as standard.
iii) Peter raised the question of what is the best way to remove the wire if the tip needs to be reformed if there is any difficulty in passing the lesion. The alternatives are to remove the wire from the polyimide tubing. This presents problems as the effective length of the device would be somewhere around 4.7m. In addition this would present problems with our stepped wire configuration as the wire cannot be removed from the polyimide. I suggested that the best solution was to remove the entire system including the delivery catheter with the wire advanced past the end of the delivery catheter and forming the wire then replacing the whole system into the guiding catheter. Peter thought this was acceptable. We should discuss this and think through the implications of this. *

The package should be rigid enough such that it can be lifted from one end without the packaging deforming. The package should be double sterile barrier wrapped and enclosed in a carton. The delivery catheter should be in a separate sterile peel-pouch in the same outer container.

2. Preparation of the device:

Peter expressed concern regarding the introduction of the cannulae and the guidewire into the polyimide tubing. He would like to see some kind of plastic funnel mechanism at both ends of the tubing which can be used to guide both of these components into the polyimide tubing. This must be easily removable. He mentioned that the carotid procedure is a highly stressful procedure, it can often take a significant period of time to get the guide catheter in place and that half-way through the procedure would not be a good time to have problems inserting the cannulae and wire into the polyimide tubing. In addition the rear section of the polyimide tubing should be clearly marked (painted white?) as the transition between the wire and the polyimide should be clearly visible to allow attachment of a pin vice for the torqueing of the wire.

The overall layout of the packaging allows introduction of the prepared device into the guide catheter by removing the delivery catheter from the race-track tray section. There must be clear finger holes in order to remove this safely from the package.

Exhibit 5

REDACTED

In summary, the changes to the current packaging specification that we have previously discussed are:

i) inclusion of a three-way tap.
ii) clear marking for the proximal end of the polyimide tubing.
iii) the inclusion of a funnel type device on each end of the polyimide tubing in order to facilitate introduction of a cannulae and guidewire.
iv) Double sterile wrap
v) Finger holes for removal of delivery catheter

Other Comments

Peter voiced concern regarding the capture of embolic particles in vessels where the balloon had not been correctly sized. It is important that no alternative flow pathways exist. He expressed concern over the performance of the device in low-flow situations. The guiding catheter will partially occlude the carotid artery reducing flow. The most important time for the capture of embolic particles will the initial flow passing the lesion on deflation of the balloon or removal of the stent delivery system - this will be in all probability the highest level of embolic particulate matter. Therefore the performance of the device as the flow starts is critical.

With regard to the volume of embolic material Peter is general agreement that this is likely to be low. If there was significant embolic material liberated during these procedures it is unlikely that the procedure would have got to this stage because the stroke rate would be much higher and the type of strokes would be much more significant. We do need to measure this as we have discussed and will investigate the models available to us.

Peter is interested in getting Sheffield involved in the initial studies as a key clinical site. I said that I would discuss this with Gary Roubin and ensure that his interest is known.

Regards

Chas

REDACTED

REDACTED

LAKE REGION MANUFACTURING
European Marketing & Sales Ltd.
Anchor House, 6b Crofton Terrace, Dun Laoghaire, County Dublin, IRELAND
FAX: 353-1-2808627 TELEPHONE: 353-1-2808580

TO: Mr. Paul Gilson
MedNova
Fax: 091 758272

FROM: Tom Kleist
Lake Region

DATE: REDACTED

SUBJECT: Request for Quote

FAX TRANSMISSION COVER SHEET

Dear Paul,

Attached please find your quotation for both the Ontrac and CCA .013"/.016" guidewires.

The quotation for the .013"/.016" guidewire contains two prices. The $1,500 lot charge would cover our development costs including all engineering and tooling/fixturing costs. The $32.00 per unit price is our best estimate based on production manufacturing cost. This price will be reviewed after the development stage to determine if we can justify reducing the $32.00 price.

Paul, please let me know if you would like to proceed with this project. Lake Region should be able to provide prototype in about 4 weeks. I will be returning to the States this Saturday. After REDACTED I can be reached at 612/448-2511 or via fax at /612/448-7012

361

Sincerely

Tom Kleist
Manager, Sales & Service

REDACTED

Exhibit 7

REDACTED REDACTED MEDNOVA LTD @003

INVOICE

NUMBER

1560

DATE

REDACTED

Lake Region Manufacturing, Inc.
Telephone: (612) 448-5111
FAX: (612) 448-6692

Mail Remittance To:
P.O. Box 117
Chaska, MN 55318-0117

SHIP DATE:

MNA
MEDNOVA LTD.
UNIT 3, IDA ENTERPRISE PK
TUAM ROAD
GALWAY
ATTN:
IRELAND

SHIPPED TO

MEDNOVA LTD.
UNIT 3, IDA ENTERPRISE PK
TUAM ROAD
GALWAY

ATTN:
IRELAND

IPPED VIA	FOB	FREIGHT	TERMS
NT L P1	CHASKA, MN	~~COLLECT~~ Pre-paid	NET 30 DAYS

Y	CUSTOMER P.O. NUMBER	ITEM/DESCRIPTION	ORDER/CONTROL NUMBER	UNIT PRICE	EXTENDED AMOUNT
)	7360	MNA-001-01K EA MNA-001-01K PKG-CCA .013/.016 300CM	905986-00	.00000	.00)0
1	7360	MODEL SP LT MODEL SP PROTOTYPE LOT CHARGE	905986-00	1500.00000	$ 1500.00
	TOTAL QUANTITY	SHIPPED: 21			
		- END OF INVOICE -			
		1 CARTON, 2 LBS MEDICAL GUIDEWIRES			

)0.00	.00	.00	.00	.00	.00	$ 1500.00

LLOW A DISCOUNT OF .00

URNS AFTER 90 DAYS.
URNS MUST HAVE A
AUTHORIZATION NUMBER.

E CERTIFIED TRUE AND CORRECT

REDACTED REDACTED MEDNOVA LTD 004

INVOICE

PAGE 1

Lake Region Manufacturing, Inc.
Telephone (612) 448-5111
FAX (612) 448-3441

Mail Remittance To:
P.O. Box 117
Chaska, MN 55318-0117

REDACTED

INVOICE NO. 906455-00
INVOICE DATE
DATE SHIPPED REDACTED

MEDNOVA LTD.
UNIT 3, IDA ENTERPRISE PK
TUAM ROAD
GALWAY
ATTN:
IRELAND

REDACTED

MEDNOVA LTD.
UNIT 3, IDA ENTERPRISE PK
TUAM ROAD
GALWAY
ATTN:
IRELAND

HASE ORDER NO.	REDACTED	SHIP VIA	FOB	FREIGHT	
		FED INT'L P1	CHASKA, MN	PRE-PAID	

MS ALLOW DISCOUNT OF $ .00

	DESCRIPTION	UNIT	ORDERED	SHIPPED	B/O	PRICE	EXTENSION
HT	CHARGES	LT	1	1	0	.00000	.00

- END OF ORDER -

BILLING FOR FREIGHT CHARGES FOR ORIGINAL INVOICE
905986-00 THAT SHIPPED ON REDACTED

REDACTED

INVOICE	DISCOUNT	TAX	FREIGHT	HANDLING	MISC	TOTAL
.00	.00	.00	51.00	.00	.00	$ 51.00

FTER 90 DAYS. ALL RETURNS MUST HAVE A RETURN AUTHORIZATION NUMBER.
/ US IMMEDIATELY OF DEFICIENCIES, IMPERFECTIONS OR NONRECEIPT OF PRODUCTS.
EDIT: ALL ITEMS MUST BE RETURNED IN ORIG. CONDITION & CONTAINERS. ALL ADJUSTMENTS SUBJECT TO OUR FACTORY.
RTIFY WE ARE CONFORMING TO THE FAIR LABOR STANDARDS ACT OF 1938 AS AMENDED.

2 Rev. 1/98 CUSTOMER COPY

PROJECT TEAM MEETING REVIEWS

Meeting Date: ...25-02-1998

Attendees: SOR, SH, PM, MG, KR, DV, JH, SE & EB

Copy: File, MC, CT, PG

Next weeks key goals	Last weeks achievements	General Responsibility
Keith Ryan		
• Define pouch seal process window • Write pouch seal procedure • Sort out PTFE rig issues • Move into clean room • Spec/Order silicone fluid	• Carried out heat seal Taguchi experiment • Tested pod tensile strengths • Trained operator on PTFE Shrink	PTFE shrink development work
Shivaun O Rourke		
• Get DPS finalised • Approve protocol for pouch sealing • Approve pod shrink protocol • Approve pouch seal protocol • Update second pod shrink validation	• Oven ready for olefin validation • Updated ease of device prep • Updated 1st pod shrink validation	Responsible for test development and validation.
Susan Eighan		
• Complete delivery cath sterility/bio build • Complete ster/bio build to balloon bond • Start balloon bonding sterility build	• Sterility build complete to balloon bond • Started sterility build for delivery catheter	-Catheter manufacturing line set up and operation in Contech, Nitinol forming & balloon bond
Padraig Maher		
• Fatigue & tensile Nitinol • Loading force measurement • Full length loading force testing • Manoeuvrability test rig	• Tested Nitinol based on primary, secondary, tertiary & quaternary failures with reduced test error. • Cycle tested Nitinol • Got samples to laser company	Core punching, core assembly and specifications
Jon Hager		
• Compile bio. Info from vendors • End of line routing approved • Inspect loading mechanism • Material issue traceability proc. Appd. • Document control procedure approved • Design review procedure approved. • Batch history review procedure approvd	• Inspected dipped balloons • Remaining routing signed off • All stock moved to Contech	-Vendor approval -Receiving goods system -Documentation -DMR Development
David Vale		
• Operator trained • Build sterility pieces • Write packaging procedure(s) • Pod screening validations complete • Evaluate corners of pod process window • Draft label design	• Pod shrink process defined broadly • Shrink process documentation issued • Ordered blank labels • Started construction of tray tool	-Labelling -Retrieval catheter -Loading mechanism -Packaging
Steven Horan		
• Bio & Remaining sterility builds • Narrow balloon wall thickness distributi • Trial with vacuum for bubbles • • Optimise process / eliminate defects •	• Analysed Taguchi results • Updated dip & core assembly procedures	Responsible for: -Balloon development
Chas Taylor		
• Labels/ IFU available for builds	• Ideally available 20/2/98 • Worst case available 3/3/98	Labelling, IFU

Exhibit 8

1.0 Purpose

This procedure outlines the method used to assemble the soluble core so that it can be used to make the chronoflex balloon.

2.0 Scope

This procedure relates to the assembly of the soluble core. This core assembly is used as a manufacturing material to produce the chronoflex balloon.

3.0 Responsibilities

3.1 It is the responsibility of the production supervisor to ensure that adequate resources are in place for all manufacturing operations and that all production duties are performed in accordance to the relevant manufacturing procedures.

3.2 It is the responsibility of the designated engineer to ensure that adequate initial training is given to all production personnel including the production supervisor and that all current procedures are in effect so that subsequent training can be performed in house by the production supervisor.

4.0 Equipment

- Core Assembly Fixture
- Oven
- 30cm Ruler
- Sharp Knife
- Petri Dishes
- Desiccator
- Silica Gel
- Swabs

5.0 Set Up

5.1 All assembly operations are to be carried out in a fume cupboard or a fume hood.

5.2 Switch the oven on and set the temperature to 60°C.

5.3 Check that the MEK solution is within its expiry date before using it.

6.0 Procedure

6.1 Using the ruler and knife cut the required amount of 80.0 ± 1.0mm lengths of soluble rod. Ensure that there is enough cut lengths to complete the entire lot.

6.2 Insert the rod into the core and place into the core assembly fixture as shown in fig. 1.0.

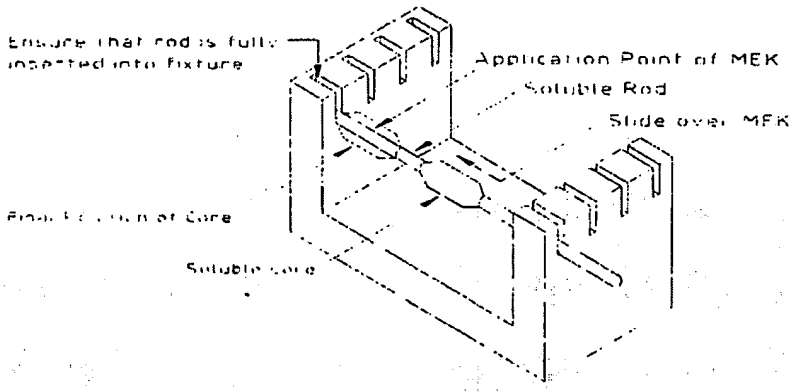


Fig. 1.0 Core Assembly Fixture

6.3 Ensure that the soluble rod is fully inserted into the fixture (ref. fig. 1.0)

6.4 Position the core so that it is approximately in the centre of the rod (ref. fig. 1.0)

6.5 Dampen the end of a swab with MEK and wipe it around the rod approximately 1cm from the wall of the fixture (ref. fig 1.0)

6.6 Slide the core along the rod as illustrated in fig 1.0. Ensure that the core is flush with the wall of the fixture and that the rod is still fully inserted into the fixture. Repeat this for the ten cores in the fixture.

6.7 Remove the assembled cores from the first fixture and place into the oven that is at 60 ± 2°C and leave for 20 hours minimum to allow all of the excess MEK to evaporate and the core assembly to dry.

6.8 After 20 hours minimum remove the core assemblies from the oven.

6.9 Place the dried cores into petri dishes in batches of 9 and place the petri dishes into the desiccator. Ensure that the Silica Gel in the desiccator is blue.

6.10 Repeat this procedure until the entire lot is complete.

6.11 Complete the lot history records.

Approvals		Date
Originator:	Steven Slevin	24/2/98
Quality and Regulatory Affairs Manager:	Mary Gallagher	25/02/98
Research and Development Manager:	Eamon Brady	25-02-98

MEDNOVA LTD..	Doc. No. Revision:	**Form QP97 001.2** **03**	Page 1 of 1
TITLE:	**Change Request Form**		

Document requiring changes

Doc. No.: MP 97 009 **Title: Soluble core assembly** **Version:05**

Required Changes:

Obsolete procedure

Justification for Changes:

Has been replaced with SA 98 077, machined Perspex core.

Training Required (Yes / No):No
(If No, justify) Document will be obsolete.

Change Requested By

Print: Steven Horan **Sign:** Steven Horan **Date:** 13/11/98

QA Review and Approval

Re-validation required:	N/A	**Screening Affected:**	N/A
Biological re-evaluation required:	N/A	**Re-screening Required:**	N/A

Comments: Inspection procedure may have to be obsoleted.

QA Engineer

Print: SHIVAUN O'ROURKE **Sign:** Shivaun O'Rourke **Date:** 13/11/98

25 th Feb 98

MEDNOVA LTD.	Doc. No. TP97022 Revision: C0	Page 1 of 2
TITLE:	Retrieval tip integrity	
	Effective Date:	Issue Date:

1.0 **Purpose**

This procedure specifies the method for determining and quantifying the integrity of the retrieval catheter tip under a compressive load.

2.0 **Scope**

This procedure applies to the unreinforced retrieval catheter tips. They will be of lengths of 100mm.

4.0 **Principle**

Measurement of the compressive force required to cause the retrieval catheter tip to buckle.

5.0 **Apparatus**

Lloyd LRX tensile testing machine
20N Load cell
Wire grips
Tensile grips
Test apparatus (wire with copper core at the end.)

6.0 **Procedure**

6.1 Fit the 20N load cell to the tensile testing machine and set the gauge length to 150mm.

6.2 Set up the sample as in the tensile testing machine as illustrated in fig 1.0. Thread the wire with copper core down through the retrieval catheter. Allow the copper core to sit 10mm from the entrance of the retrieval catheter tip.

Fig 1.0 Test set-up for retrieval tip integrity

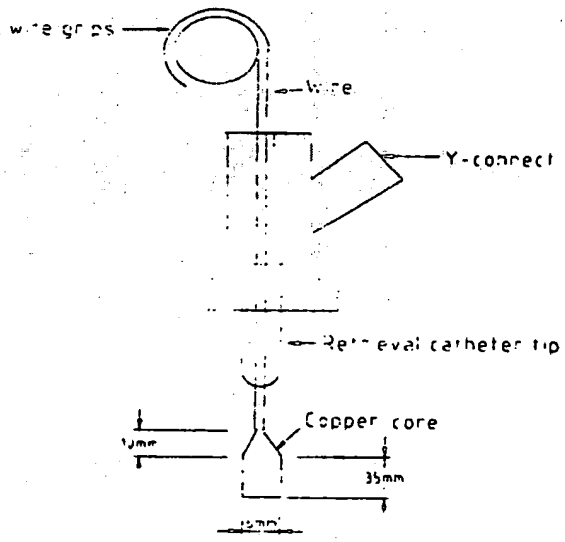


Exhibit 10

6.3 Secure the Retrieval catheter from bottom using the tensile clamp. Secure the wire from the top grip using wire grips.

6.4 Set the crosshead speed to 150mm/min. Set the load limit to 40N and the extension limit to 200mm.

6.5 Put the machine into tensile mode and initiate the test.

6.6 The test will end when the tip buckles fractured or when either the load limit or extension limit is reached.

6.7 The above procedure will be repeated for the number of samples specified.

7.0 Expression of results

The maximum force and the force required to cause the specimen to buckle will be expressed in Newtons. The strain is to be given as a percentage of the original length.

8.0 Test Report

The test report will include the following information:

- The maximum force applied to the specimen
- The force required to cause the specimen to buckle.
- The strain at break

7.0 Document Approval

Originator Date

Quality test Engineer _____ _____

Approval:

Research & Development Manager _____ _____

Quality & Regulatory Manager _____ _____

United Parcel Service of Ireland Limited

Unit 134, Slaney Close,
Dublin Ind. Estate,
Glasnevin, Dublin 11.
Tel: 01 - 830 4003
Fax: 01 - 830 4160

VAT REG No: IE 4807503K
Registered No: 113016
Registered Office: 1 Earlsfort Centre,
Lr. Hatch Street, Dublin 2.

DELIVERY INVOICE

nee Number:	3353007371	Date: 26 FEB 1998	Invoice Number: 000000604423
nee VAT-ID:		Description:	MONEL WIRE

nee / Bill to:

MEDNOVA LTD
UNIT 3. IDA ENTERPRISEPK
TUAM RD
GALWAY

Shipper:

FAIRBANKS WIRE CO
39 COMMERCIAL RD

ADDISON IL6010145
UNITED STATES

1.525.0 Currency: USD Customs Number: 1613216

Date:	Waybill Number:	Reference:	Service / Bill Type:	Exchange Rate:	Weight / Packages:
EB 1998	4539701036 2		WW EXPRESS / NON-DOCUMENT	1.38	14.5 / 1

ption of Charges

FREIGHT	:	126.49
VAT	:	43.66
DUTY	:	3.88
INSURANCE	:	
SURCHARGES	:	
OTHER CHARGES	:	
GOVERNMENT CHGS	:	

ch es 174.03

nount

mount Due 174.03

UPS

VAT ANALYSIS

Rate	Value	VAT Amount
21.00%		
00.00%	130.37	.00

Paid # 744
26-2-98

FOR CARRIER USE	AMOUNT RECEIVED	OTHER INFORMATION
ed for UPS by MIKE	☒ Cheque ☐ Cash	
e 26/2/98 Time	174.03	

Exhibit 11

PAYNE PLASTICS

C.B. PAYNE (PLASTICS) LIMITED
Inchbrook Trading Estate.
Woodchester. Stroud. Glos. GL5 5EY
Tel: 01453 835301 Fax: 01453 835151

INVOICE

VAT No. 276 1581 42

ICE ADDRESS	DELIVERY ADDRESS (IF DIFFERENT)
1067 MEDNOVA LTD UNIT 3.IDA BUSINESS PARK TUAM ROAD GALWAY REPUBLIC OF IRELAND	

E - TAX POINT	YOUR ORDER No.	OUR REF. No.	INVOICE No. 13796
26.2.98	7475	B2850	

ANTITY	DESCRIPTION	UNIT PRICE	VAT RATE	VALUE
300	MACHINED PERSPEX ROD DRG: CA97-001	REV.00 0.94	0.00%	282.00
1	DELIVERY VIA TNT EXPRESS WORLDWIDE	30.00	0.00%	30.00
	DELIVERY NOTE 17930			

RECEIVED - 4 MAR 1998

IETT BY THE 30th OF THE MONTH FOLLOWING THE MONTH OF INVOICE	TOTAL GOODS	312.00
	VAT	0.00
	TOTAL DUE £	312.00

TEREST WILL BE CHARGED ON ALL OVERDUE INVOICES AT THE RATE OF 5% /MONTH

Exhibit 12

DAWNLOUGH LTD.

Polkeen Industrial Estate,
Tuam Road, Galway. Tel: (091) 751732

RECEIVED - 6 MAR 1998

Mednova Ltd.,
IDA Business Park,
Tuam Rd.,
Galway.

Invoice

Your order number	Date sent	Invoice date	INVOICE NUMBER
	See Below	27/2/98	3660

Jantity	Description	Unit price	Amount
	11/2/98 DEL. No. 56		
I.off	Heat Gun Assy. Mod plus Nozzle		330 00 R&C
4.off	Alum Gauge Blocks (Susan)	18 00	72 00 "
I.off	Extension for Nozzle		25 00 "
	13/2/98 Del. No. 56		
2.off	Perspex Rods (PM)	24 00	48 00 "
	23/2/98 Del. No. 56		
I.off	Alum End Stop Brkt.		28 00 "
	Reg. Zero VAT		

Terms: Unless specifically quoted above. this invoice is strictly nett and due for payment within 30 days from date of despatch.
Claims regarding damaged goods or non-delivery cannot be entertained unless received within 7 days from despatch date and confirmed in writing.
Title remains with vendor until goods are paid for in full.

Sub total	503 00
VAT at 0.%	
Total due	503 00

VAT registration number: 4735115C

Exhibit 13

EUROflex®

COMPONENTS AND MICRO-TECHNOLOGIES

EUROFLEX Schüßler GmbH
Kaiser-Friedrich-Straße 7
D-75172 Pforzheim

Telefon (07231) 92 75 24
Telefax (07231) 92 75 25

EUROFLEX Schüßler GmbH · Postfach 14 40 · D-75114 Pforzheim

Mednova Ltd.
Attn. David Vale
Unit 3, IDA Enterprice Park
Tuam Road
Galway, Rep. of Ireland

27. Feb 98

Invoice 98-40021

laser cut parts from Nitinol tubing (slit tube)
according drawing CE 97 003, Rev. 04,
Your PO Number: 7394
Packing Slip 98-30001

		Unit Price	Lot Price
200 pieces	**10 mm long**	**15 DM**	**3.000 DM**
		Total	**3.000 DM**

Your Vat# IE8242533I
VAT Exempt#: 11/03235/1098
Our Ust#: DE181403500

Please pay to:
BW-Bank Pforzheim
SWIFT CODE: BWBKDE6S666
Account#: 4824334900

Exhibit 14

EUROflex®
SMART COMPONENTS AND MICRO-TECHNOLOGIES

EUROFLEX Schüßler GmbH
Kaiser-Friedrich-Straße 7
D-75172 Pforzheim

Telefon (072 31) 92 75 24
Telefax (072 31) 92 75 25

EUROFLEX Schüßler GmbH · Postfach 14 40 · D-75114 Pforzheim

Mednova Ltd.
Attn. David Vale
Unit 3, IDA Enterprice Park
Tuam Road
Galway, Rep. of Ireland

27. Feb 98

Invoice 98-40020

laser cut parts from Nitinol tubing (slit tube)
according drawing CE 97 003, Rev. 04,
Your PO Number: 7483
Packing Slip 98-30037

		Unit Price	Lot Price
250 pieces	**10 mm long**	**15 DM**	**3.750 DM**
		Total	**3.750 DM**

Your Vat# IE8242533I
VAT Exempt#: 11/03235/1098
Our Ust#: DE181403500

Please pay to:
BW-Bank Pforzheim
SWIFT CODE: BWBKDE6S666
Account#: 4824334900

MEDNOVA LTD.	Doc. No. Form QP97 012.1 Revision: 00	Page 1 of 1
TITLE:	Purchase Order	

MedNova Ltd
Unit 3, IDA Enterprise Park,
Tuam Road,
Galway, Rep. of Ireland.
Tel: Int +353 (0)91 758288
Fax: +353 (0)91 758272

PURCHASE ORDER

The following number must appear on all related correspondence, shipping papers, and invoices:
P.O. NUMBER: 7518

To:	Ship To:
ASHFIELD SPRINGS (RON KOCH)	Above Address

P.O. DATE	REQUISITIONER	SHIP VIA	F.O.B. POINT	TERMS
27-02-98	D. VALE	—	C.I.F.	STD

QTY	UNIT	DESCRIPTION	UNIT PRICE	TOTAL
200		CLOSED COIL STAINLESS STEEL SPRING AS PER SPEC: CD97 002 REV Ø TO BE DELIVERED TO MEDNOVA BY THURSDAY MARCH 12TH	£2.96	£592

SUBTOTAL	£592
VAT	—
SHIPPING & HANDLING	
OTHER	
TOTAL	

VAT: IE 8242533I
VAT EXEMPT NO: 11/03235/1098

1. Please send two copies of your invoice
2. Enter this order in accordance with the prices, terms, delivery method, and specifications listed above.
3. Please notify us immediately if you are unable to ship as specified.

Eileen Doyle 3-3-98
Authorised by Date

Exhibit 15

MedNova Ltd.
Unit 3, IDA Enterprise Park,
Tuam Road, Galway, Ireland.
Tel: 353 (0) 91 758288
Fax: 353 (0) 91 758272
e-mail: mednova@iol.ie

MedNova

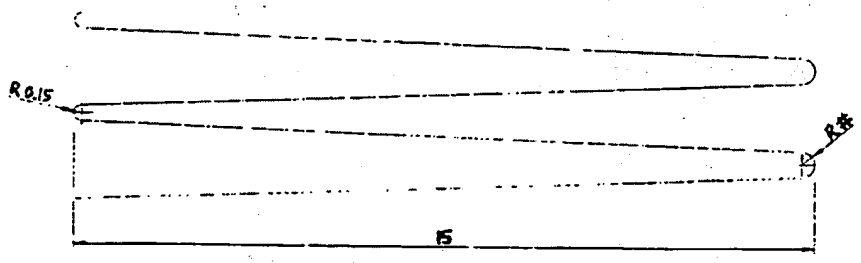
(4)

FAX

To:	Ger O'Carroll, Adam Spence	**From:**	David Vale
Fax:	079 63039	**Pages:**	1
Phone:	079 63038	**Date:**	27/02/98 ~~24/02/98~~
Re:	PO 7510	**CC:**	

Ger,

Please find attached a purchase order for the spline press tool which will be capable of producing the two designs shown below:



Profile A: R# = 0.15mm
Profile B: R# = 0.25mm

Regards,

David Vale

Exhibit 16

National Heat Treatment Centre
Department of Mechanical Engineering
University College Dublin
Belfield
Dublin 4

Ph: (01) 7061760 / 7061832
Fax: (01) 7061736
e-mail: heat.treatment@ucd.ie

30th March 1998

3853

MedNova Ltd
Unit 3
IDA Enterprise Park
Tuam Road
Galway

INVOICE

To heat treatment as per your request:

Date	Order No.	Pcs	Material	Weight	Price
5/3/98	7524		Monel (anneal)		£40.00
				Total	**£40.00**

Please make cheque payable to "National Heat Treatment Centre".

Thank you.

RECEIVED 31 MAR 1998

Part Funded by the European Regional Development Fund through the Office of Science and Technology

Exhibit 17

Medical Profiles, Inc.
12743 MERRIMAN RD.
LIVONIA, MI 48150
(313) 422-2211; (313) 422-0385

INVOICE

RECEIVED - 9 MAR 1998

PAGE

SOLD TO
MEDNOV
MEDNOVA LTD.
UNIT 3 IDA ENTERPRISE PK
TUAM ROAD GALWAY
REP OF IRELAND

SHIP TO
MEDNOVA LTD.
UNIT 3 IDA ENTERPRISE PK
TUAM ROAD GALWAY
REP OF IRELAND

DATE	SLSPN	ORDER NO.	ORD. DATE	SHIPPED VIA	TERMS	INVOICE N
03/02/98		7504	02/27/98	FEDERAL EXPRESS	UPON RECEIPT	00005

ITEM / DESCRIPTION / SERIAL NO.	QUANTITIES	UNIT	UNIT PRICE	AMOUN
CC97002 HEMOSTASIS Y-CONNECTOR MPI LOT #004128	Ordered .0000 Shipped 171.0000	PCS	5.2900	904.

(R) per SE

REMIT TO: PO BOX 510354 LIVONIA MI 48151

NON-TAXABLE	TAXABLE	SALES TAX	FREIGHT	MISC.	INVOICE TOTAL
904.59	.00	.00	.00	.00	904.59

Exhibit 18

INVOICE

Medical Profiles, Inc.
12743 MERRIMAN RD.
LIVONIA, MI 48150
(313) 422-2211 • (313) 422-0385

RECEIVED 16 MAR 1998

SOLD TO
MEDNOV
MEDNOVA LTD.
UNIT 3 IDA ENTERPRISE PK
TUAM ROAD GALWAY
REP OF IRELAND

SHIP TO
MEDNOVA LTD.
UNIT 3 IDA ENTERPRISE PK
TUAM ROAD GALWAY
REP OF IRELAND

DATE	SLSPN	ORDER NO.	ORD. DATE	SHIPPED VIA	TERMS	INVOICE NO
03/11/98	66	7504	03/11/98	FEDERAL EXPRESS	UPON RECEIPT	00005645

ITEM / DESCRIPTION / SERIAL NO.	QUANTITIES	UNIT	UNIT PRICE	AMOUNT
CC97 002 HEMOSTASIS, Y-CONNECTOR W/LUER MPI LOT #004148	Ordered .0000 Shipped 829.0000	PCS	5.2900	4385.41

REMIT TO: PO BOX 510354 LIVONIA MI 48151

NON-TAXABLE	TAXABLE	SALES TAX	FREIGHT	MISC.	INVOICE TOTAL
4385.41	.00	.00	.00	.00	4385.41

4 - Mar - 98

MedNova Ltd.
Validation screening 07

Process: SHRINKAGE OF PTFE ONTO COPPER MANDREL FOR THE FORMATION OF THE LOADING MECHANISM

Prepared by: _____ _____

Quality Engineer

Approved by:
Quality and Regulatory Affairs manager: _____ _____

Research and Development manager:

_____ _____

Exhibit 19

1.0 Purpose

1.1 This validation screening protocol describes the requirements of the process to shrink PTFE shrink tubing onto a 150mm copper mandrel for the formation of a sub-component for the loading mechanism. The purpose of this validation screening is to determine a process window for the shrinkage of PTFE onto the copper mandrel. The parameters affecting the shrinkage of PTFE onto the copper mandrel are temperature and time.

2.0 Scope

This validation testing covers the Installation Qualification and validation screening for the shrinkage of PTFE onto the copper mandrel.

3.0 Process Description

This process relies on a loading mechanism rig to shrink the PTFE tubing onto the copper mandrel, an oven for shrinking the teflon tubing and a stretching rig to remove the PTFE from the copper mandrel. Lengths of 85mm of 0.083" PTFE shrink tubing are slid over 1/3 the length of a grit blasted tube. This is then slid over the copper mandrel and set up in the loading mechanism rig as described in Manufacturing Procedure MP98 001. The rig is then placed in an oven. Subsequent to the shrinkage of the PTFE, the copper mandrel is removed by stretching it using the stretching rig.

4.0 Responsibility

4.1 It is the responsibility of the Quality test engineer for developing protocols, determining sample sizes, number of repetitions, assisting the R&D engineer in determining appropriate process challenge conditions and to oversee the activities required by the protocol. The R&D engineer will be responsible for overseeing the activities required by the protocol, for monitoring and compiling results and for communicating all non-conforming situations to the Quality test engineer and the relevant Managers.

5.0 Installation Qualification

5.1 Installation Qualification establishes the procedures to be followed for evaluating the equipment design, determination of calibration requirements and identifying critical equipment features that could affect the effectiveness of the process.

5.2 The following equipment is to be verified during the Installation Qualification phase:-

5.2.1 Equipment/Instruments

5.2.1.1 **Auxiliary Equipment**

- High temperature oven
- loading mechanism rig
- Stopwatch
- copper-stretching rig

5.2.1.2 **Measuring Instruments**

- Lloyd LRX tensile test machine
- Meter rule

5.2.2 **Equipment Installation**

The following service is required to run the Oven:

- Electrical supply 3 phase (380) volts

Verification that the above service is correctly installed will be provided in a utilities installation report and included as appendix to the screening validation report.

5.2.3 **Control system**

The software associated with the tensile testing machine will be tested to verify compliance with the tensile machine readouts. Verification of testing carried out by the manufacturer will also be made available and will be included as an appendix to the screening report.

5.2.4 **Preventative Maintenance**

A monthly maintenance check will be carried out on the copper stretching rig and the loading mechanism fixture and recorded in a maintenance log book. Maintenance will ensure that there is no deviation from the performance of these tools. Verification that maintenance has been carried out prior to validation screening will be provided by including a copy of the maintenance report sheet as an appendix to the screening validation report.

5.2.5 **Calibration**

Calibration Certificates for the following instruments must be reviewed to ensure that each item is calibrated, if records are unavailable or if the item is out of calibration then that item must be calibrated. If for any reason calibration is not possible, then an explanation will be provided.

5.2.5.1 **Auxillary equipment**

- Stopwatch
- Oven

5.2.5.2 **Measuring Equipment**

- 20N load cell on Lloyd LRX tensile test machine
- Meter rule

5.2.6 **Raw Material Qualification**

5.2.6.1 The following materials are required for this process.

- PTFE tubing.
- Copper mandrels
- Grit blasted hypo-tubing

Verification that the correct products will be used in the screening validation will be provided by inclusion of the incoming inspection report for the specified lot of product and Raw material specification in the appendix of the screening validation report.

5.2.7

Specification/Documentation /Drawings	Document no's
Raw material spec for PTFE 0.083"	CB97008
Raw material Spec for Grit blasted hypo-tubing	CE97004
Raw material spec for copper mandrels 0.048"	CK97013
Test method	As per protocol
Manufacturing procedure for shrinking of teflon onto the copper mandrels.	MP98001

table 5.2.7

5.2.8 Training Requirements

5.2.8.1 The training requirements of all personnel who manufacture subassemblies to be used in the screening validation and who will perform testing will be verified as completed and adequate by the relevant Manager prior to initiation of screening.

5.2.9 Conclusion to Installation Qualification Phase

5.2.9.1 The Installation Qualification phase of the report shall summarise all data used to support analysis and conclusions made (calibration records) . The supporting data shall be included as appendix to the report. Reference to sections in this validation screening shall be made as appropriate in the report.

5.2.9.2 All documentation, data and checklists shall be reviewed and verified.

5.2.9.3 The Installation phase for the validation screening shall be considered complete on the successful fulfilment of all relevant sections of this validation protocol and verified by supporting data.

5.2.9.4 If all requirements of the Installation Qualification Phase are satisfied then the pre-validation screening will proceed to the next phase, validation Screening testing phase.

6.0 Validation Screening

6.1 Assurance will be required by documented verifications that all aspects of the installation Qualification have been successfully completed prior to commencing the screening test performance phase.

6.2 The purpose of this phase of validation screening is to establish the process window for the shrinkage of PTFE on to silver plated copper mandrels and to challenge worst case parameters that represent those extreme conditions likely to be encountered in production.

7.0 Worse case conditions

7.1 There are two key process performance parameters which determine the quality of the shrinkage of PTFE to the spring shaft . These are as follows:

- Temperature
- Time

The parameter settings associated with this process that will produce worst case conditions requiring challenge are, the lowest temperature, shortest time and the highest temperature and longest time.

7.2

Parameters	Worst case upper	Nominal	Worst case lower
Temperature(°C)	355	350	345
Time (mins)	6.5mins	6 mins	5.5mins

table 7.2

These worst case upper & lower limits are based on the operating range obtained during pre-validation screening. Based on the information described in the above table, process variables worst case upper & lower will be tested to approximately challenge the process.

7.3 Sampling Rationale

A sample size of twenty units will be chosen for screening. The rationale for this is that this sample size allows us to confidently analyse the population distribution in relation to the tensile strength of PTFE to the grit blasted hypo-tubing and the visual appearance of the PTFE. This sample size is based on engineering tests which have been carried out. A summary of these engineering tests will be included as an appendix to the screening protocol.

7.4 Screening test procedure

Twenty units of PTFE will be shrunk onto to copper mandrels, at both the worst case upper and worst case lower conditions as specified in table 7.2 The raw material used to manufacture the samples will be of the same constituents as will be used to produce finished product. The product will be tested in a non-sterile form.

7.5 Inspection

7.5.1 Inspection tests as described below will be performed for shrinking the PTFE onto the spring shafts at each worst case variable setpoint noted in table 7.2

7.6 Defect descriptions

Test inspection	Reference Documents	Defect description
Visual	N/A	• Teflon must be shrunk along 1/3 the length of the grit blasted hypo-tubing • Teflon must be evenly shrunk over the copper mandrels with no wrinkles
Physical	TP97009 DPS97001	• Upper 95%/99% CI of the PTFE integrity graph of 5 newtons.

Table 7.6

7.7 Test Method for measuring PTFE Integrity and its bond strength to the grit blasted hypo-tubing..

7.7.1 Each unit will be tested as per Lloyd LRX tensile test machine using calibrated 20N load cell for testing the sub-component. The test set up is illustrated in fig1.0.

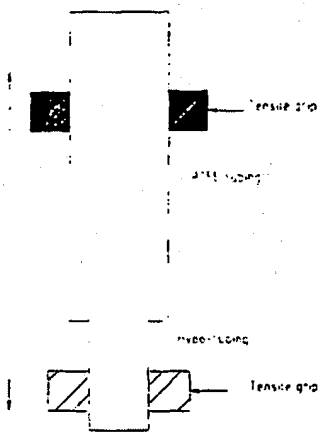


Fig 1.0 Set up for testing PTFE integrity

7.7.2 The test speed will be 100mm/min using a gauge length of 20mm. The extension limit will be 20mm and the load limit 20 newtons.

7.7.3 The machine will be programmed to calculate the maximum force required to break the bond between the Teflon and the hypo tubing and the extension at break.

7.7.4 Results will be expressed as follows: Maximum force at break in newtons and extension at break in mm.

7.7.5 The results of the test will be recorded and included as attachments to this screening validation. All units must pass a force which has been specified in section 6.

7.8 Results

All test results will be recorded using the format outlined in appendix 2.
Should any units tested fail the test they will be examined and if necessary an appropriate investigation carried out to establish why this was the case and validation screening will be started again.

7.9 Validation screening Acceptance criteria

The acceptance criteria is zero defects.

7.10 Conclusion to Qualification Phase

7.10.1 The Screening Qualification report shall summarise all data used to support analysis and conclusions made. The supporting data shall be included as appendix to the report. Reference to sections in this protocol shall be made as appropriate in the report.

7.10.2 If all requirements of the screening test Phase are not satisfied then the validation screening will be suspended and an investigation will be conducted to determine the cause and corrective actions required. The results of an investigation and any subsequent corrective actions will be documented and included in the file for this Screening validation. The screening tests will then be revised, re-approved and rerun.

7.10.3 The validation screening report will specify the process control programme to be followed to ensure that no deviation from the validated process takes place.

7.10.4 All elements of this screening protocol will be met to ensure a successful validation screening of this process and the approval of the report.

8.0 Appendices

The following documents are contained in the appendix of this protocol

- Installation qualification checklist — Appendix 1
- Test results log — Appendix 2
- Utilities & installation report — Appendix 3

Appendix 1

Installation Qualification checklist

Section 1: Equipment Installation	Yes	No	Verification Date	Verification Document
• Correct installation of • Electrical supply	_____	_____	_____	_____

Section 2: Equipment Calibration	Yes	No	Verification Date	Verification Document
• 20N load cell	_____	_____	_____	_____
• Stopwatch	_____	_____	_____	_____
• Oven	_____	_____	_____	_____

Section 3: Specification/ Drawings	Yes	No	Verification Date	Verification Document
• Test method procedure	_____	_____	_____	_____
• Manufacturing procedure.	_____	_____	_____	_____
• Spec copper mandrels	_____	_____	_____	_____
• Spec for PTFE	_____	_____	_____	_____
• Spec for hypo-tubing	_____	_____	_____	_____
• Maintenance reports for loading mechanism rig	_____	_____	_____	_____
• Incoming inspection reports	_____	_____	_____	_____

Section 4 Training	Yes	No	Verification Date	Verification Document
• Training procedure	_____	_____	_____	_____
• Training reports	_____	_____	_____	_____

Installation Confirmed By: _____ Date: _____

_____

Appendix 2

Test Results Description:
Run No:
Temperature:
Time:
Worse case upper

Sample No.	Test run	Visual	Max load(N)	Extension at maximum load (mm)	Inspection Pass/Fail
unit 1					
unit 2					
unit 3					
unit 4					
unit 5					
unit 6					
unit 7					
unit 8					
unit 9					
unit 10					
unit 11					
unit 12					
unit 13					
unit 14					
unit 15					
unit 16					
unit 17					
unit 18					
unit 19					
unit 20					

Table 1

Mean:
Standard deviation:
K value:
CI 95/99:

Test Results Description:
Run No:
Temperature:
Time:
Worse cast lower

Sample No.	Test run	Visual	Max load(N)	Extension at maximum load (mm)	Inspection Pass/Fail
unit 1					
unit 2					
unit 3					
unit 4					
unit 5					
unit 6					
unit 7					
unit 8					
unit 9					
unit 10					
unit 11					
unit 12					
unit 13					
unit 14					
unit 15					
unit 16					
unit 17					
unit 18					
unit 19					
unit 20					

Table 2

Mean:
Standard deviation:
K value:
CI 95/99:

Tested By: _____
Date tested: _____

Test equipment: _____ Calibration number: _____
_____ _____
_____ _____

Appendix 3

Utilities & installation Report for the high temperature oven

The following services have been correctly installed and verified as complete.

Electrical supply	

Signed By: _____
Date: _____

Approved By: _____
Date: _____

Ashfield Springs Limited
Registered Office:
Nunn Brook Rise,
County Industrial Estate,
Huthwaite,
Nottingham
NG17 2PD.
Telephone: Mansfield (01623) 455500 or 455501
Fax No: (01623) 455502

INVOICE

Invoice No: 432171

CUSTOMER:-

MedNova Ltd
Unit 3, IDA Enterprise Park
Tuam Rd, Galway
Rep. of Ireland

DELIVERY ADDRESS:-

MedNova Ltd
Unit 3, IDA Enterprise Park
Tuam Rd, Galway
Rep. of Ireland

E.MAIL ADDRESS - sales@ashfield.springs.com

CUSTOMER ORDER No.	ACCOUNT No.	SALES ORDER No.	PAGE	TAX DATE	PACKING NOTE No.
7518	MED4	624873	1	18/ 3/1998	530061

Ship Via: CUSTOMERS CARRIER

PRODUCT CODE	DESCRIPTION	QUANTITY	UNIT OF ISSUE	UNIT PRICE	AMOUNT	VAT
)7002,	CLOSED COIL SPR AS SPEC	220.00		2.9600	651.20	
ıment,	VAT REF. IE 8242533I					

NOTES & INFORMATION

THANK YOU FOR YOUR ORDER - TERMS NETT 30 DAYS

TITLE PASSES WHEN PAID IN FULL

GOODS	651.20
VAT	
TOTAL	STG. 651.20

Reg. No. 006

ALL ORDERS ARE SUPPLIED SUBJECT TO ASHFIELD SPRINGS LTD.
'GENERAL TERMS AND CONDITIONS OF SALE'.
A COPY OF WHICH HAS BEEN SUPPLIED TO YOU.
FURTHER COPIES OBTAINABLE ON REQUEST.

VAT Reg. No. 379 2756 02
TERMS: NETT 30 DAYS

BACS DETAILS: Sort Code - 20-63-25
A/c No. - 80128805

Exhibit 20

MedNova Ltd
Unit 3, IDA Enterprise Park,
Tuam Road,
Galway. Rep. of Ireland.
Tel: Int +353 (0)91 758288
Fax: +353 (0)91 758272

PURCHASE ORDER

The following number must appear on all related correspondence, shipping papers, and invoices:
P.O. NUMBER: 7524

To:	Ship To:
NATIONAL HEAT TREATMENT CENTRE, UCD. (THIERRY SCHWARZ)	Above Address

P.O. DATE	REQUISITIONER	SHIP VIA	F.O.B. POINT	TERMS
3.03.98	DAVID VALE	—	C.I.F.	STD

QTY	UNIT	DESCRIPTION	UNIT PRICE	TOTAL
		ANNEALING OF MONEL 400 WIRE Ø0.057" x 9" – 320 PARTS Ø0.059" x 9" – 500 PARTS Ø0.061" x 9" – 170 PARTS Ø0.063" x 9" – 500 PARTS Ø0.065" x 9" – 490 PARTS PLEASE KEEP EACH SIZE PACKED SEPERATELY.		£40

SUBTOTAL	£40
VAT	—
SHIPPING & HANDLIN	
OTHER	
TOTAL	

VAT: IE 8242533I
VAT EXEMPT NO: 11 / 03235 / 1098

1. Please send two copies of your invoice
2. Enter this order in accordance with the prices, terms, delivery method, and specifications listed above.
3. Please notify us immediately if you are unable to ship as specified.

D. Vale — Authorised by
3/3/98 — Date

Exhibit 21

PROJECT TEAM MEETING REVIEWS

Meeting Date: ...05-03-1998

Attendees: SOR, SH, PM, KR, DV, JH, SE & EB

Copy: File, MC, CT, PG

Next weeks key goals	Last weeks achievements	General Responsibility
Keith Ryan		
• Define pouch seal process window • **Sort out PTFE rig issues** • Finish load mech sterility/bio build	• Wrote pouch seal procedure • Moved into clean room • Speced/Ordered silicone fluid	PTFE shrink development work
Shivaun O Rourke		
• **Approve pod shrink protocol** • Approve pouch seal protocol (X2) • Update second pod shrink validation • Include master plan in validn. Procedure • Review maintenance system • Write software validation protocol	• Drafted pouch seal protocol • 8 Calibration procedures written • Touhy Borst validation for signoff	Responsible for test development and validation.
Susan Eighan		
• **Build 10 FP's for Ohki** • Complete del. cath sterility/bio build • Start balloon bonding sterility build • Engineering tests on UV • Move core removal to Contech • Finalise core removal process • Train Contech staff	• Completed ster/bio build to balloon bond • Built del cath sterility to pod	-Catheter manufacturing line set up and operation in Contech, Nitinol forming & balloon bond
Padraig Maher		
• Fatigue & tensile Nitinol • Analyse loading data • Define balloon wrap method	• Loading force measurement testing • Full length loading force testing • Shipped sterility build pieces	Core punching, core assembly and specifications
Jon Hager		
• **Resolve Zeus PTFE issues** • Compile bio. Info from vendors • End of line routing approved • Inspect loading mechanism • Review inspection procedures for sterility build • Inspect sterility product • Approve vendor listing	• Material issue traceability proc. Appd. • Document control procedure approved • Design review procedure approved. • Batch history review procedure approvd	-Vendor approval -Receiving goods system -Documentation -DMR Development
David Vale		
• Update retrieval catheter spec • **Order 50 retrieval cath bench test parts** • Operator trained • Build sterility pieces • Write packaging procedure(s) • Pod screening validations complete • Evaluate corners of pod process window	• Drafted label design	-Labelling -Retrieval catheter -Loading mechanism -Packaging
Steven Horan		
• Bio & Remaining sterility builds • Build 10 balloons for Ohki • **Define process and update document'n**	• Narrowed balloon wall thickness distribution • Completed trial with vacuum for bubbles • Optimise process to eliminate defects	Responsible for: -Balloon development
Chas Taylor		
• Labels/ IFU available for builds	• Ideally available 20/2/98 • Worst case available 3/3/98	Labelling, IFU

Exhibit 22

2nd Mar 98

MEDNOVA LTD..	Doc. No. Revision:	**CK98 XXX** **00**	Page 1 of 5
TITLE:	**Manoeuvrability Fixture**		
	Effective Date:	Issue Date:	

1.0 Purpose

The specification in this document describes a template which simulates the path likely to be taken by a guide catheter in reaching the site of a carotid intervention.

2.0 Background

This template is based on a study of the path taken by a guide catheter in reaching a point in the carotid artery distal to the bifurcation. The study was carried out on MedNova's circulatory system model. The model consists of a glass aortic arch which approximates the size and shape of the aortic arch, the abdominal aorta, and the iliac arteries. The femoral is simulated with a silicone tube attached to the iliac artery. The start of the left and right common carotid arteries and the left subclavian extend from the aortic arch. The bifurcation of the carotid is simulated in glass also and is connected to the main section of the model with a silicone tubing.

The path was studied by making an incision in the left femoral and passing the guide catheter into the femoral. The incission point is represented by point 0,0 on the template. The catheter was pushed up the femoral, iliac and into the abdominal arch. The point 138,135 represents the starting point of the catheter curve at the aortic bifurcation. The point 210,170 represents the end of the curve. The catheter lies against the right wall of the aorta at the base. However, the catheter pushes to the left wall of the aorta in the region close to the aortic arch. This transition is described by the points 305,170 394,148 and 467,148. In its most toutuous configuration the catheter stays on the left wall of the aorta around the aortic arch. The aortic arch is described by points 467,148 492,209 and the radius 35mm. The catheter then makes a sharp turn into the brachiocephalic artery and this turn is described by

Exhibit 23

points 492,209 505,232 and radius 25mm. The points 505,232 540,253 and 570,257 describe the path from the brachiocephalic artery to the right common carotid artery.

This is the guide catheter path to be used in testing MedNova devices for use in carotid interventions. It represents the most tortuous path possible in the glass model described above. The glass model is likely to represent worst case as its walls are hard and this makes the radius of curvature tight. It is also presumed that vessel tortuousity will not significantly alter the catheter path since the guide catheter will find the shortest path once the tortuous areas have been crossed.

3.0 Physical Properties

- Description : Fixture of Guide catheter path to Carotid Interventional site.
- Dimensions: A dimensional description of the guide catheter path is detailed in Fig. 1.
- Shape: In the manufacture of the fixture it must be ensured that the guide catheter follows the path defined in Fig.1. The guide catheter is fastened to a flat sheet with plastic clips or it may be glued. The radii of curvature must remain constant at all times so as to ensure consistency of the data generated. Fig. 2 shows the guide catheter fastened to a perspex sheet.

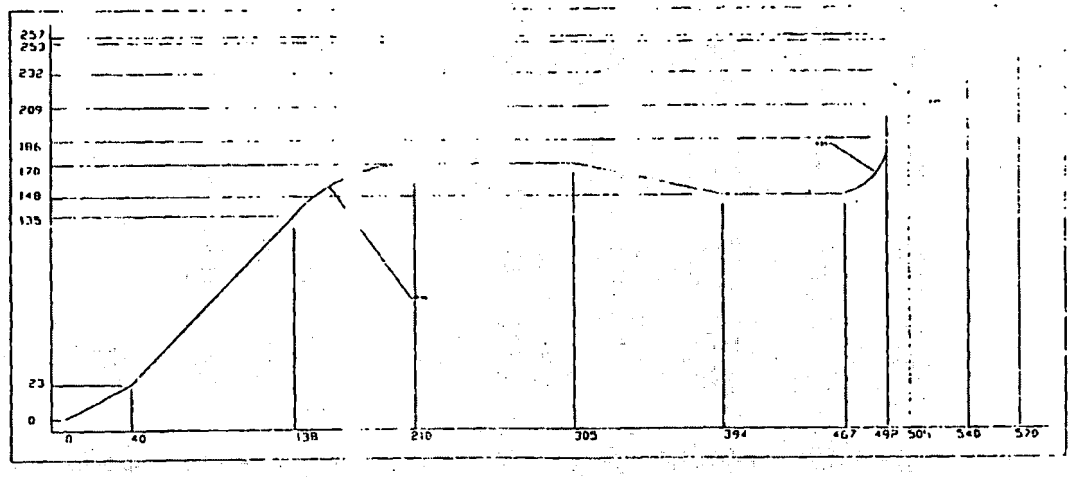


Fig. 1 Template of Guide Catheter path from femoral to carotid.

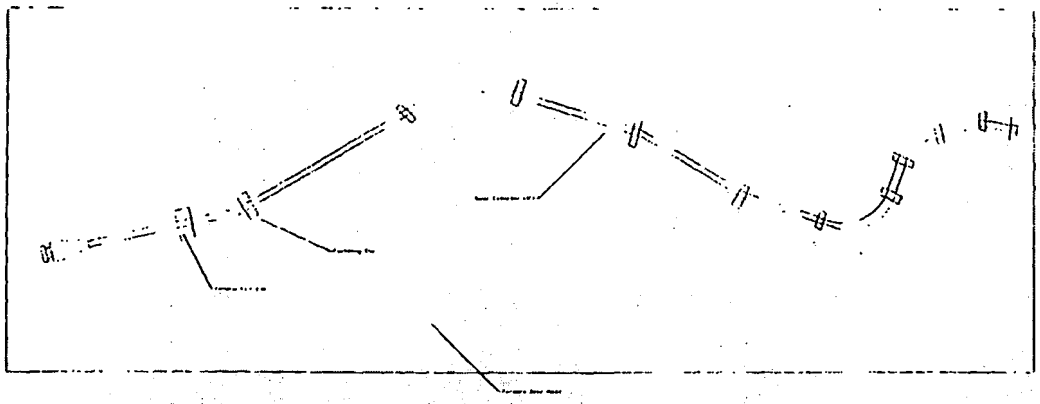


Fig 2: Manoeuvrability Test Fixture

Approvals

Originator: _____

Reaearch and Development Manager: _____

Quality and Regulatory Affairs Manager: _____

2 - Mar - 98

MedNova Ltd.	Ref.No. Revision	TP97 017	Page 1 of 3
Title	Catheter Manoeuvrability		
	Effective Date:	Issue Date:	

1.0 Purpose

This procedure outlines a method for determining the manoeuvrability characteristics of a catheters.

2.0 Scope

This test procedure can be applied to either catheter shafts or retrieval catheters.

3.0 Principle

The manoeuvrability characteristics of a material are a measure of the ease at which the material can get from one end of the tortuous pathway to the other end of the tortuous pathway. A materials manoeuvrability will depend on two characteristics, these are the materials push characteristics and the materials tracktability characteristics. A materials pushability characteristics is in effect a measure of the resistance a material will have when pushed along a tortuous pathway. The tracktability of a material is in effect a measure of it's ability to take the shape of the tortuous pathway. A very tracktable material will take the longest route along a tortuous pathway, whereas a very pushable material will take the shortest possible route along the tortuous path. A 1.2m length of catheter shaft is inserted into the tortuous pathway, relatively little force is required to manoeuvre .93m of the catheter shaft. At this point the catheter shaft has reached the base of the last arc on the tortuous pathway as shown in fig 1.0 and it is at this point that the force at which the shaft is manoeuvred gets much greater. It is at this critical point that the force must be measured. The force obtained at this point will be the true measure of the ease at which the catheter shaft can be manoeuvred through the tortuous pathway.

4.0 Apparatus

Fixture consisting of a tortuous path PM no. 001
Lloyd LRX tensile testing machine
20N load cell
Tensile clamping grips.

5.0 Materials

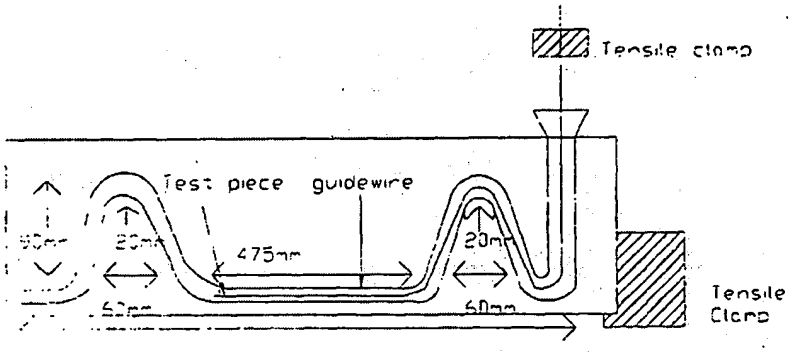
1.2m of catheter shaft
1.2m of retrieval catheter
1.2m of guide catheter.

6.0 **Procedure**

6.1 Fit the 20N load cell to the machine and put the machine into compression mode.

6.2 Set the gauge length to 50mm. Place the tortuous path as shown in fig.1 . into the clamps.

Fig. Test apparatus for manoeuvrability



6.4 Clamp the test piece into the top grip and allow .93m of the test piece to extend into the opening of the tortuous path and secure it using the top tensile clamp. The test piece is measured using a meter rule and marked with a black marker to indicate the .93m mark.

6.5 Set the crosshead speed to 100mm/min. Set the extension limit to 50mm and the load limit to 2N.

6.6 Do not program the machine to return automatically. The machine should be programmed to calculate the maximum force.

6.7 Start the test, once the original gauge length is passed the test will stop, at this point loosen the top grip, hold the test piece in place and return the top grip to its original location.

6.8 Tighten the top grip and start the same test again. The Procedure should be repeated until the test piece emerges from the bottom of the tortuous path, this will take approximately 4 test runs.

6.9 The results should be put together as one set of results and the graphs for each test overlaid. This procedure should be repeated for whatever sample number of test pieces are specified..

7.0 **Test Report**

The test report should include the following information

(i) The maximum force required to push the shaft through the test block.
(ii) The number of samples tested
(iii) The type of shaft tested

8.0 **Expression of Results**

The results should be expressed in Newtons and are a function of the force required to push the catheter shaft through a tortuous path..

9.0 **Document Approval**

Originator		Date
Quality test Engineer	_____	_____

Approval:

Research & Development Manager	_____	_____
Quality & Regulatory Manager	_____	_____

2 - Mar - 98

MedNova ltd.	Ref. No.		Page 1 of 3
	Revision:	00	
Title:	Calibration of Flow meters on the Circulatory rig		
	Effective Date:	Issue Date:	

1.0 **Purpose**

To outline a method by which the flow meters on the circulatory rig will be calibrated.

2.0 **Scope**

The scope of this procedure is to outline how flow meters used to measure the flow rate through the circulatory rig will be calibrated.

3.0 **RESPONSIBILTY**

The Quality Engineer is responsible for all Mednova Ltd. calibration related to product quality.

4.0 **Equipment**

Flow meter
Circulatory rig
Beaker
Calibrated Electronic weighing scales.
Calibrated stopwatch
Metal clips
Tubing

5.0 PROCEDURE

5.1 Disconnect one end of the simulated carotid artery from the main circulatory rig as shown in fig 1.0. Connect the simulated artery to one end of the flow sensor and attach a piece of tubing onto the other end of the flow sensor.

5.2 Turn the pump on the circulatory rig on. Allow the tubing attached to the flow sensor to drain into a bowl.

5.3 Tighten a metal clip on the tubing which is attached to the flow sensor to reduce the volume of flow through the tube. Keep tightening until the reading on the flow meter is 12L/min.

5.4 Place the tube as shown in fig 1.0 into the beaker at one time interval as indicated on the flowmeter, simultaneously press a stopwatch.

5.5 Note all subsequent readings on the flowmeter after this and record in appendix 1.

5.6 After the tenth reading, disconnect the tube from the beaker, place it back into the bowl and calculate the average flowmeter reading.

5.7

5.8 Weigh the beaker of water collected using the electronic weighing scales.

5.9 Convert the weight of the water(g) into flowrate(L/min)using the following formula :

$$\frac{\text{Total flow rate readings /10}}{1000} \times 60 \times 60$$

5.6 This is carried out three times for a flow rate of 12L/min.

5.7 Repeat steps 5.3 to 5.9 for a flow rate of 6l/min.

5.8 If results of the calibration are found to meet the acceptable tolerances as specified in the calibration report log then the results are approved and signed. sticker is then placed on the flow meters.

The water bath circulates the water in waves to allow for even distribution of temperature.

5.3 Place a temperature probe which is connected to a digital thermometer into the hot a water bath.

5.4 Place 1000mls of cold water into the bath to cover all the temperature probes.

5.5 Allow to settle for 5 minutes and note the reading observed on the digital thermometer and also on the chart recorder.

5.6 Take out about 100mls of the cold water and add 100mls of boiling water to the water bath. Repeat step 5.5.

5.7 Repeat step 5.6 five times, taking out 100mls of water each time and adding 100mls of boiling water. Allow the water to settle each time for five minutes and note the readings.

5.8 Compare the results obtained from the chart recorder to the digital Thermometer.

5.9 If results of calibration are found to meet acceptable tolerances as specified in the calibration report log then the results are approved and signed. A calibration sticker is then placed on the temperature probes.

6.0 Records

6.4 Records of calibration are kept in a designated area by Quality Assurance.

7.0 **Document Approval**

Originator _____ Date _____

Quality test Engineer _____ _____

Approval:

Research & Development Manager _____ _____

Quality & Regulatory

Manager _____ _____

Calibration of Temperature probes type K

	Temperature probe 1	Temperature probe 2	Digital Thermometer	Error
Cold water				
1st 100ml				
2nd 100ml				
3rd 100ml				
4th 100ml				
5th 10ml				

Accuracy of Digital Thermometer & probe
Accuracy of temperature probe
Calibrated on:
Calibration due:
Calibrated by:
Uncertainty of measurement:

Comments:

3-3-98

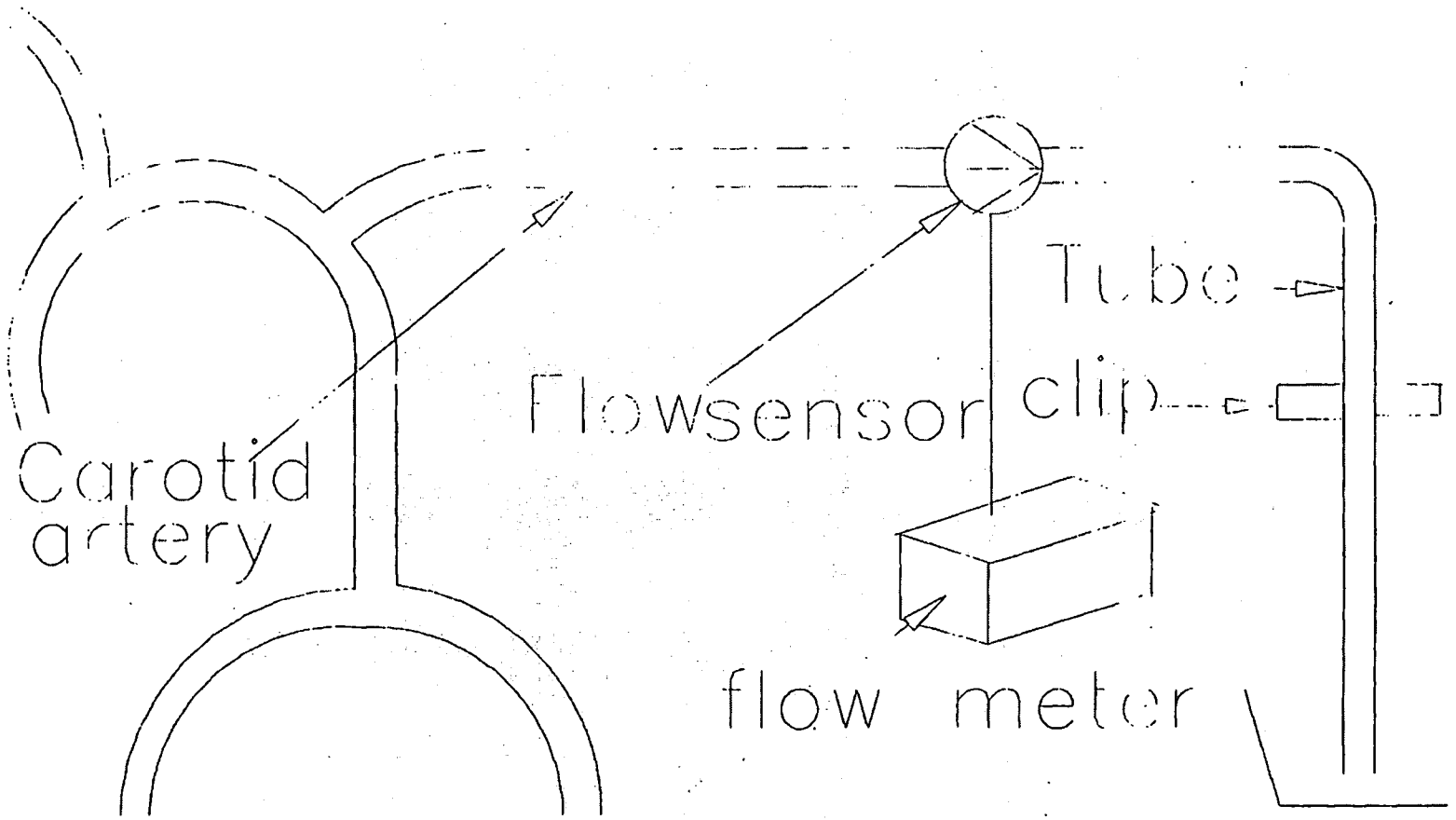


Exhibit 26

4 - Mar - 98

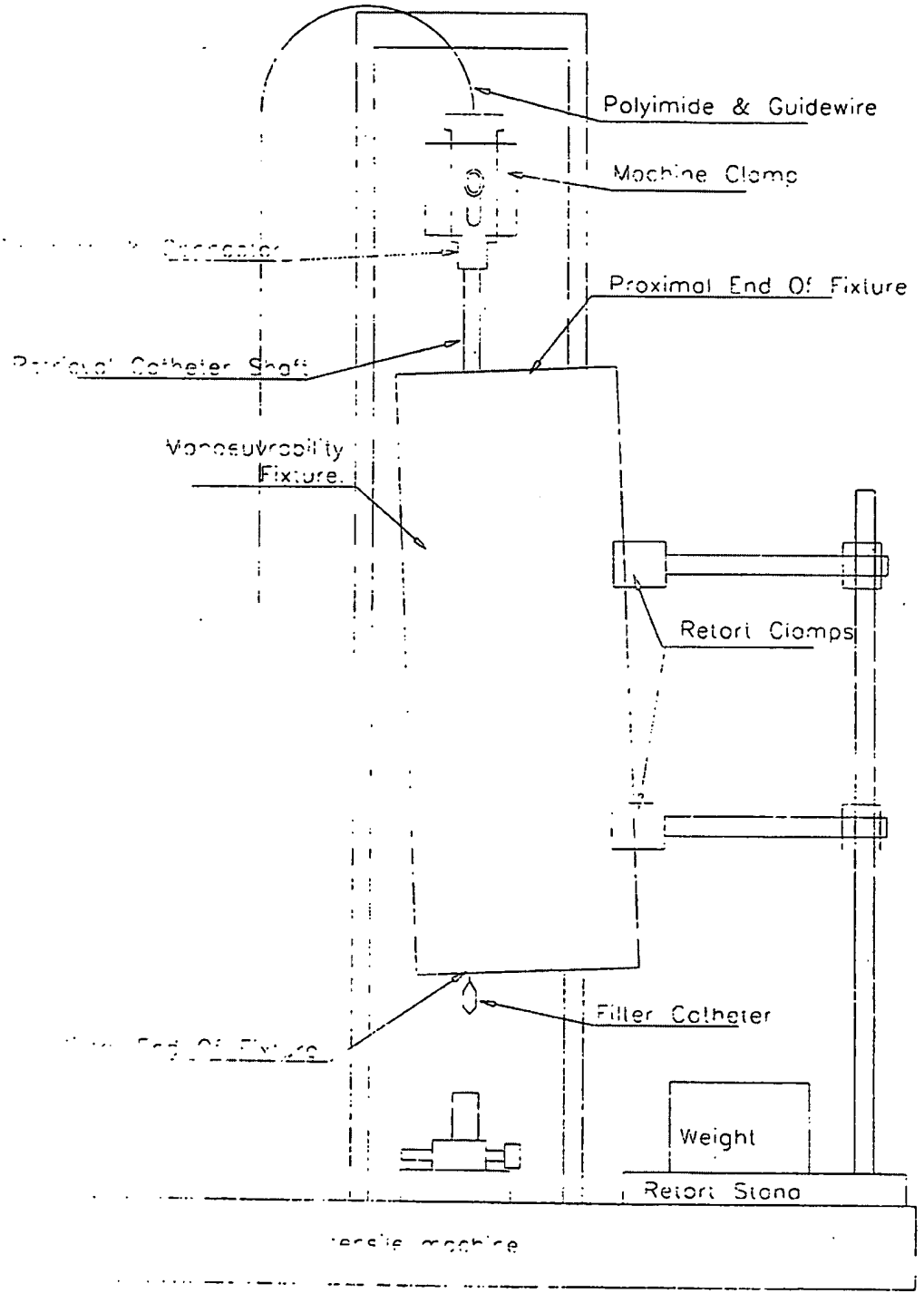
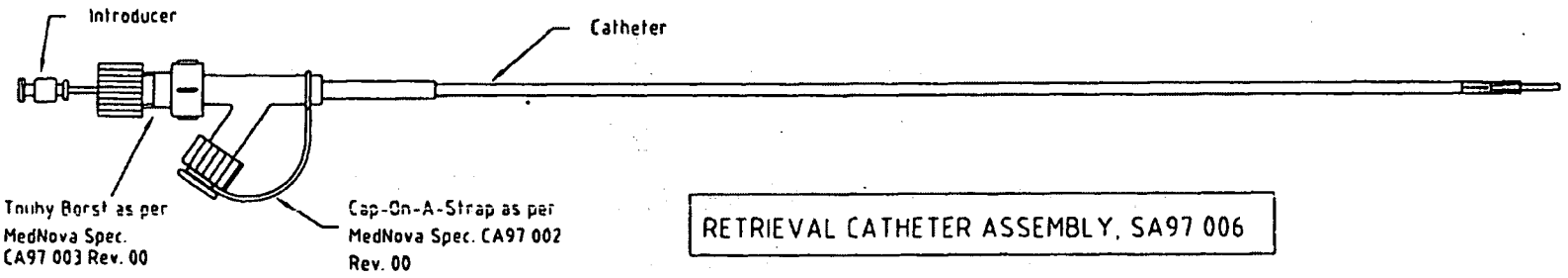
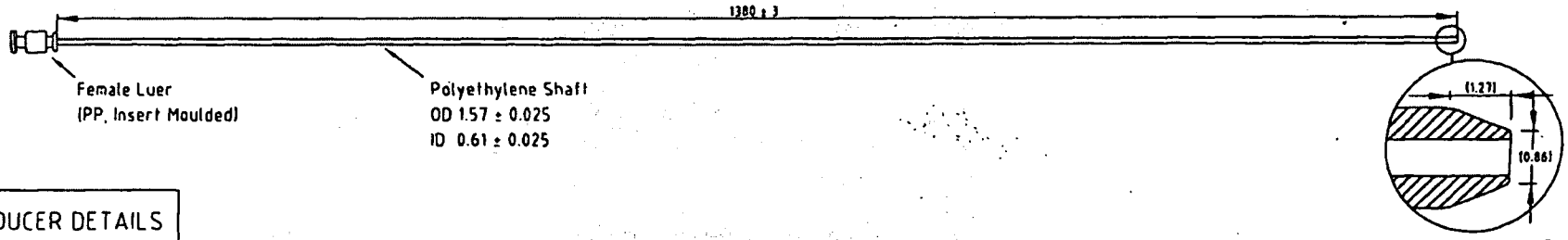


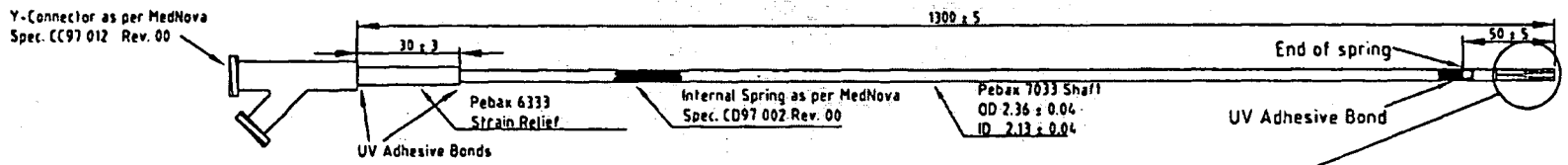
Exhibit 27



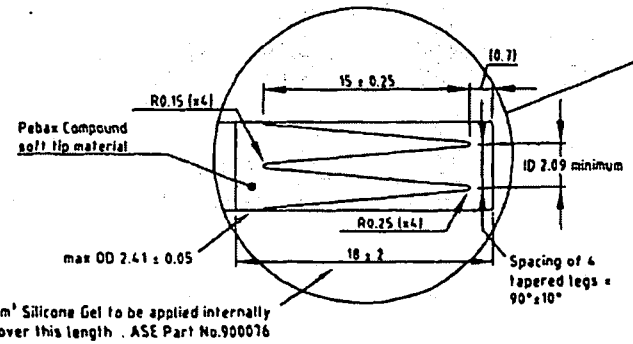
RETRIEVAL CATHETER ASSEMBLY, SA97 006



INTRODUCER DETAILS



NOTES:
1. Catheter to be clean and free from damage or deformation.
2. Catheter soft tip surface to be smooth and free from embedded matter or any evidence of protrusion of tapered legs.
3. No tapered leg material to be present in the distal tip of the catheter.
4. No delamination to occur between soft tip material and tapered legs.



CATHETER DETAILS

MedNova Ltd.	
All Dimensions in mm	
Drn. By: D.V.	SA97 006 Rev. 2
Date: 06-03-'98	Attachment 1.0

Exhibit 28

MEDNOVA LTD.	Doc. No.	Form QP97 012.1	Page 1 of 1
	Revision:	00	
TITLE:	Purchase Order		

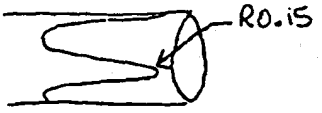
MedNova Ltd
Unit 3. IDA Enterprise Park,
Tuam Road,
Galway. Rep. of Ireland.
Tel: Int +353 (0)91 758288
Fax: +353 (0)91 758272

PURCHASE ORDER

The following number must appear on all related correspondence, shipping papers, and invoices:
P.O. NUMBER: 7540

To:	Ship To:
ADAM SPENCE LTD. (GERO'CARROLL)	Above Address

P.O. DATE	REQUISITIONER	SHIP VIA	F.O.B. POINT	TERMS
6-03-98	D. VALE	—	C.I.F.	STD

QTY	UNIT	DESCRIPTION	UNIT PRICE	TOTAL
10	1	RETRIEVAL CATHETER ASSEMBLY AS PER SPEC SA 97006 Rev 02, EXCEPT: TAPERED LEG TIPS TO BE R0.15 (NOT R0.25):  (DELIVERY DATE: APRIL 3rd 1998)	£23.70	£237

SUBTOTAL	£237
VAT	—
SHIPPING & HANDLIN	
OTHER	
TOTAL	

VAT: IE 8242533I
VAT EXEMPT NO: 11 / 03235 / 1098

1. Please send two copies of your invoice
2. Enter this order in accordance with the prices, terms, delivery method, and specifications listed above.
3. Please notify us immediately if you are unable to ship as specified.

6-3-98
Authorised by Exhibit 29 Date

MEDNOVA LTD.	Doc. No.	Form QP97 012.1	Page 1 of 1
	Revision:	00	
TITLE:	Purchase Order		

MedNova Ltd
Unit 3, IDA Enterprise Park.
Tuam Road.
Galway. Rep. of Ireland.
Tel: Int +353 (0)91 758288
Fax: +353 (0)91 758272

PURCHASE ORDER

The following number must appear on all related correspondence, shipping papers, and invoices:
P.O. NUMBER: 7539

To:	Ship To:
ADAM SPENCE (LEE O'CARROLL)	Above Address

P.O. DATE	REQUISITIONER	SHIP VIA	F.O.B. POINT	TERMS
6-03-98	D. VALE	—	C.I.F.	STD

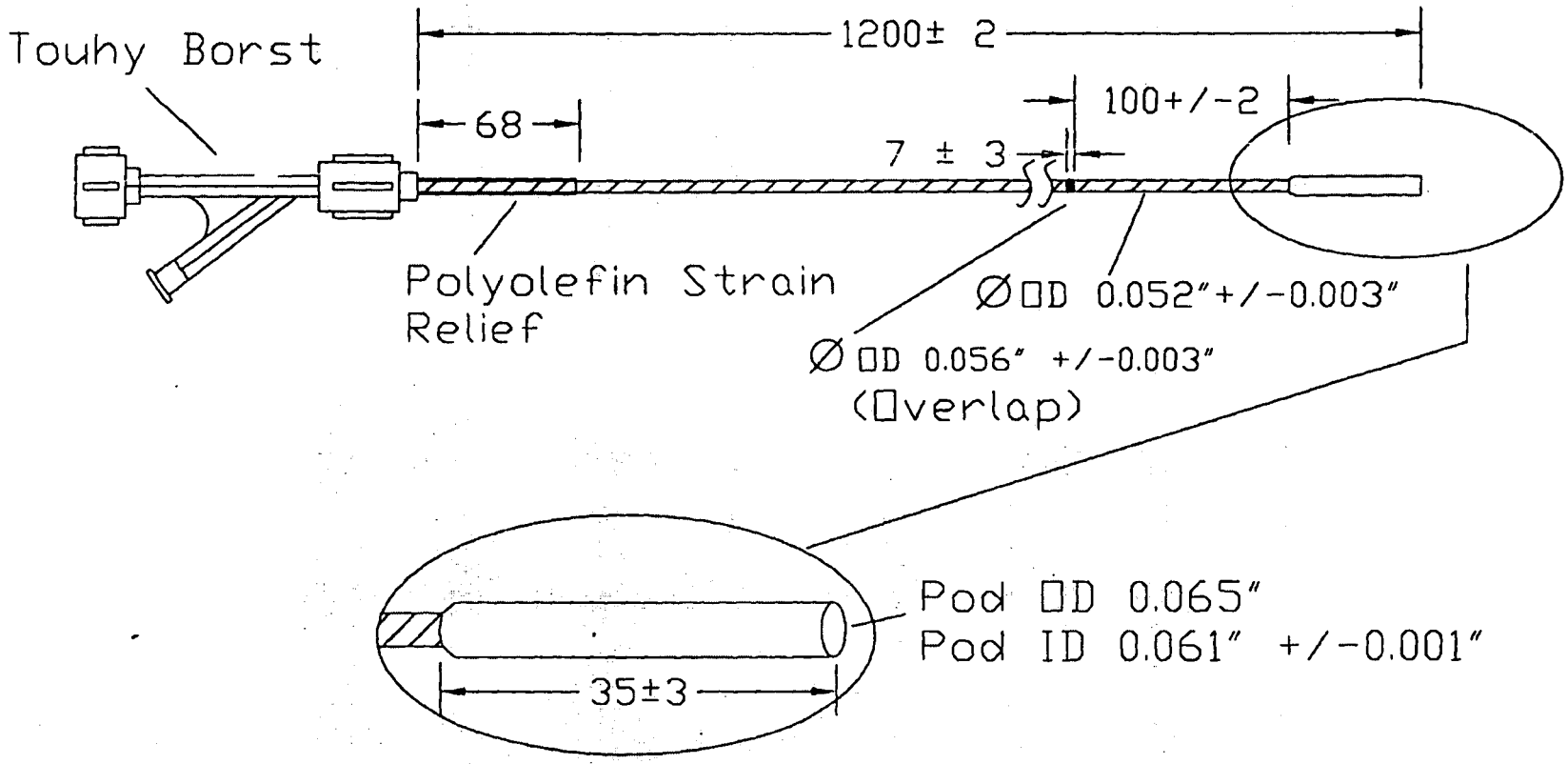
QTY	UNIT	DESCRIPTION	UNIT PRICE	TOTAL
50	1	RETRIEVAL CATHETER ASSEMBLY AS PER SPEC SA97006 REV 02. (DELIVERY DATE: APRIL 3rd 1998)	£23.70	£1,185

SUBTOTAL	£1.185
VAT	—
SHIPPING & HANDLIN	
OTHER	
TOTAL	

VAT: IE 8242533I
VAT EXEMPT NO: 11 / 03235 / 1098

1. Please send two copies of your invoice
2. Enter this order in accordance with the prices, terms, delivery method, and specifications listed above.
3. Please notify us immediately if you are unable to ship as specified.

Eoin Boyd 6-3-98
Authorised by Date



NOTES :

- Catheter to be clean and free from any damage, deformation or kinks
- PTFE and polyolefin to be smoothly and completely shrunk over the spring shaft, without wrinkles or splits.
- PTFE Pod to be straight and free from wrinkles or other distortion.

SA98 006 Rev 01	
CATHETER SHAFT Sub-Assembly Drawing	
Date: 09/03/98	Un-specified Dimensions in mm
Attachment 1.0	Drawn By : Keith Ryan

Exhibit 30

Facsimile Message **Private and Confidential**

To: **Paul Gilson, Gary Roubin**
Fax: **00 1 212 585 2762**
From: **Chas Taylor**
Subject: **Directions to Montefiore**
Date: **11.03.98**

As discussed meet at Montefiore at 9.00am. I may be a little later but will see you there. Gary - will you bring enough equipment to do three cases, we will probably only do two on the day. Naturally we will reimburse you for costs.

Directions:

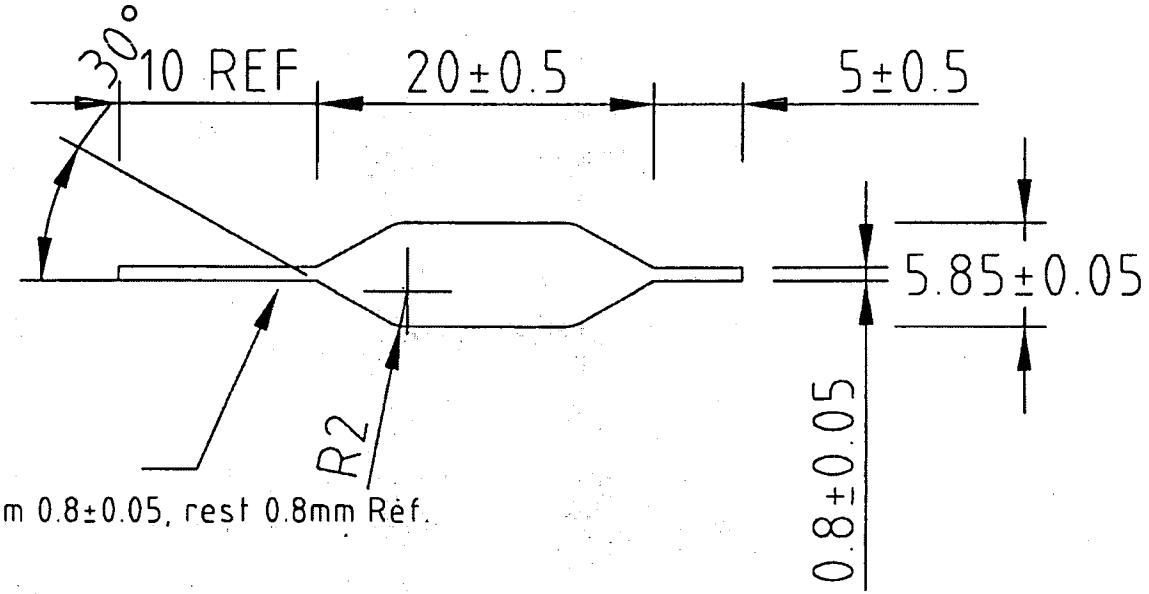
FDR to Major Deegan Freeway - North to exit 13 [233rd Street]. Ramp is on RHS - proceed towards light at top of ramp but 10 yds before light is slip road on RHS. Take this - you will now be heading South on Jerome Avenue.

Approx. ½ mile you will go under subway - carry on through two or three sets of lights to GUN HILL ROAD. Turn left and Hosp is 400 yds on RHS at top of hill. Go past building to lights turn right on Bainbridge and right again on 210th Street. Main entrance is 111E "10th Street.

Dr. Ohki office no is.	718 920 4707
Home	718 548 1258

Chas.

Exhibit 31



Diameter on first 3mm 0.8±0.05, rest 0.8mm Ref.

SOLUBLE CORE (9)	CC98 001 Rev. 01
ATTACHMENT 1	All Dimensions in mm
Draughted By: Steven Horan 09/03/98	

Exhibit 32

PROJECT TEAM MEETING REVIEWS

Meeting Date: ...11-03-1998

Attendees: SOR, SH, PM, KR, DV, JH, SE, MC, PG & EB

Copy: File, CT

Welcome Back Mairsil.

Next weeks key goals	Last weeks achievements	General Responsibility
Keith Ryan		
• Define pouch seal process window • **Sort out PTFE rig issues** • Finish load mech sterility/bio build • Pod screening of overlap joint complete	• Updated loading mech. Documentation for silicone fluid • Build 10 Ohki loading mechanisms	PTFE shrink development work
Shivaun O Rourke		
• **Approve pod shrink protocol** • Approve pouch seal protocol (X2) • Update second pod shrink validation • Include master plan in validn. Procedure • Write software validation protocol • Polyolefin validation started	• Reviewed maintenance system • Pouch seal in signoff	Responsible for test development and validation.
Susan Eighan		
• Start balloon bonding sterility build • **Resolve teflon shrink process issues** • Move core removal to Contech • Finalise core removal process • Train Contech staff • UV bonding studies • Put process controls in place for nitinol cracking issue	• Buildt10 FP's for Ohki • Complete del. cath sterility/bio build • Started engineering tests on UV	-Catheter manufacturing line set up and operation in Contech, Nitinol forming & balloon bond
Padraig Maher		
• Retest new loading mech design • Write up nitinol test results • **Evaluate deployment & retrieval force** • Define balloon wrap method	• Fatigued & tensiled Nitinol • Analysed loading data	Core punching, core assembly and specifications
Jon Hager		
• Compile bio. Info from vendors • **End of line routing approved** • Inspect loading mechanism • Inspect sterility product • Approve vendor listing • Train J. Mc Donagh on inspections • QA Inspections	• Significant package of bio info compiled • Reviewed inspection procedures for sterility build	-Vendor approval -Receiving goods system -Documentation -DMR Development
David Vale		
• **Pod engineering studies complete** • Approve package procedures • Order printed labels for bench testing	• Updated retrieval catheter spec • Ordered 50 retrieval cath bench test parts • Operator trained • Built sterility pieces • Wrote packaging procedures	-Labelling -Retrieval catheter -Loading mechanism -Packaging
Steven Horan		
• Analyse balloon data • **Evaluate balloon strengths** • Dip balloons for UV bonding trials • Order cores from CP and US	• Bio & Remaining sterility build complete • Built 36 balloons for Ohki • Defined process outline and update document'n	Responsible for: -Balloon development
Chas Taylor		
• Labels/ IFU available for builds	• Ideally available 20/2/98 • Worst case available 3/3/98	Labelling, IFU

Exhibit 33

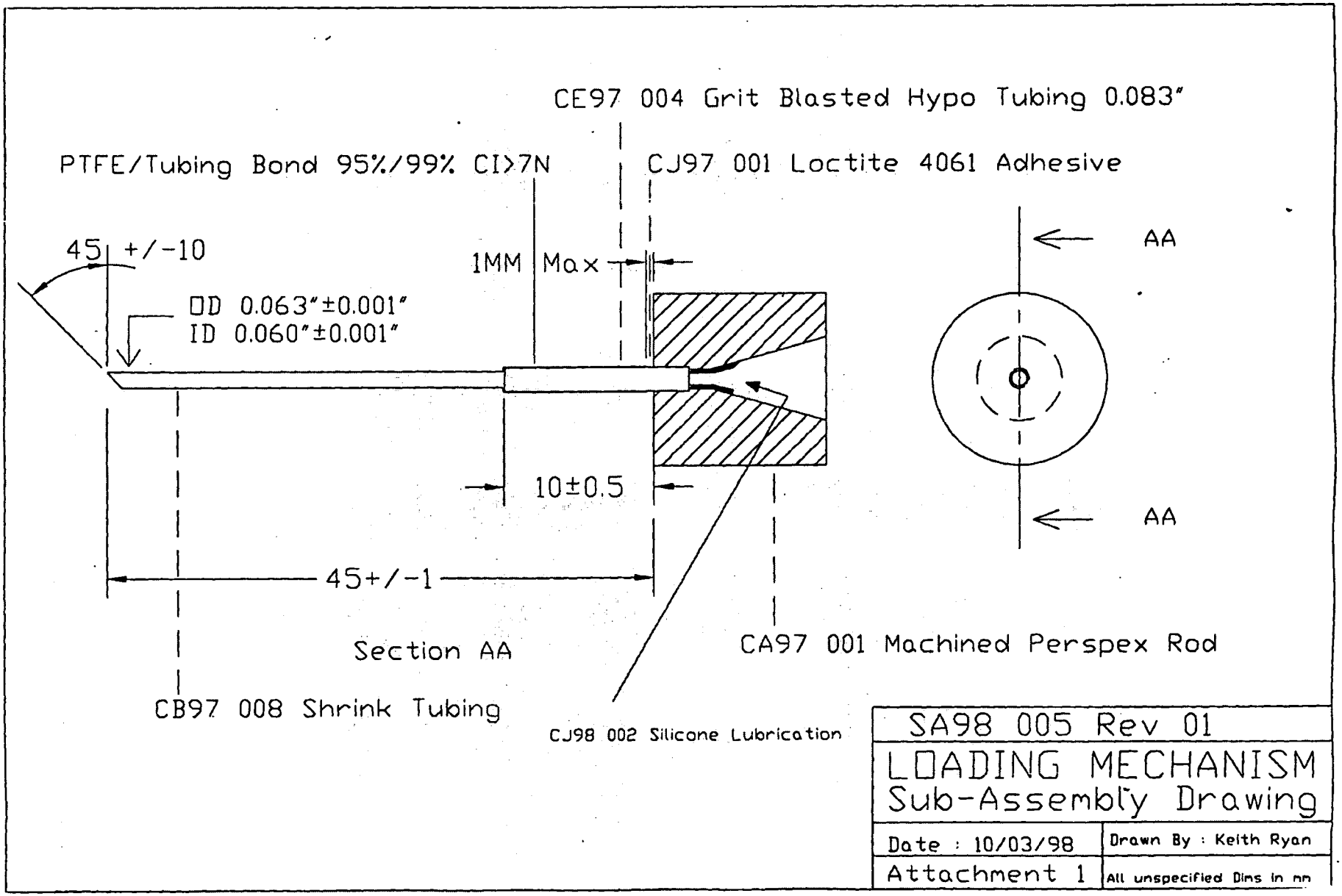

CE97 004 Grit Blasted Hypo Tubing 0.083"
PTFE/Tubing Bond 95%/99% CI>7N
CJ97 001 Loctite 4061 Adhesive
45 +/-10
1MM Max
OD 0.063"±0.001"
ID 0.060"±0.001"
AA
AA
10±0.5
45+/-1
Section AA
CA97 001 Machined Perspex Rod
CB97 008 Shrink Tubing
CJ98 002 Silicone Lubrication
SA98 005 Rev 01
LOADING MECHANISM
Sub-Assembly Drawing
Date : 10/03/98
Drawn By : Keith Ryan
Attachment 1
All unspecified Dims in mm

Exhibit 34

QOSINA

COMMERCIAL INVOICE

Date: March 13, 1998

SOLD TO:	SHIP TO:
MEDNOVA LTD. Unit 3, IDA Enterprise Park, Tuam Road, Galway REP. OF IRELAND	- S A M E -

Attn: Mr. David Vale

PURCHASE ORDER NO: 7517

These commodities, technologies or software were exported from the U.S. in accordance with the Export Administration Regulations. Diversion contrary to U.S. law prohibited.

DESCRIPTION	QUANTITY (PCS.)	PRICE PER THOUSAND	TOTAL PRICE
# 83010 - Y Connector With 2 Female Luers, 3.2mm	500	$ 225.00	$ 112.50
(PLASTIC COMPONENTS BULK, NON-STERILE)		TOTAL:	$ 112.50

TOTAL BOXES SHIPPED:	ONE (1)
COUNTRY OF MANUFACTURE:	FRANCE
CUSTOMER VAT #:	IE8242533I
SHIP VIA:	UPS EXPRESS "collect"
COMMODITY:	3926.90.9060
EX WORKS :	Edgewood, New York, U.S.A.

AUTHORIZED SIGNATURE:

Magdalena Petrov
Logistics

150-Q EXECUTIVE DRIVE, EDGEWOOD, NEW YORK 11717-8329 U.S.A.
PHONE (516) 242-3000 • FAX (516) 242-3230
info@qosina.com • www.qosina.com

Exhibit 35

QOSINA CORPORATION
150-Q EXECUTIVE DRIVE
EDGEWOOD, NEW YORK 11717
PHONE: (516) 242-3000 FAX: (516)242-3230

* * * P A C K I N G L I S T * * *

CUSTOMER ORDER NUMBER	DATE	SHIPPED VIA	SALESPERSON
7517	Mar 13 98	UPS - EXPRESS "cc"	NLP

SHIP TO: MEDNOVA LTD.
Unit 3, IDA Enterprise Park
Tuam Rd., Galway
REP. OF IRELAND
(VAT# IE 8242533I)

BILL TO: MEDNOVA LTD.
Unit 3, IDA Enterprise Park
Tuam Rd. Galway
REP. OF IRELAND

Quantity	Qosina Part Number and Description of Component
500	#83010 - Y connector with 2 female luers, 3.2mm LOT #: Q4287 mw CPN: CC97012 Rev.0

*** ALL DOCUMENTATION ATTACHED TO OUTSIDE OF MASTERCARTON #1
ONE SET OF DUPLICATES INSIDE CARTON. NO OTHER DOCS INCLUDED
IN CARTON #2 - ***

Cartons	Order Complete	Balance to Follow
1	Yes	No

THANKS FOR YOUR ORDER!

QOSINA
150-Q EXECUTIVE DRIVE
EDGEWOOD, NY 11717-8329
TEL: (516) 242-3000
FAX: (516) 242-3230
http://www.qosina.com
EMAIL: accounting@qosina.com

INVOICE

DUE DATE: 4/15/98

NO.:	28685
DATE:	3/16/98
PAGE:	1

SOLD TO:

MEDNOVA LTD.
Unit 3, IDA Enterprise Park
Tuam Rd. Galway
REP. OF IRELAND

SHIP TO:

MEDNOVA LTD.
Unit 3, IDA Enterprise Park
Tuam Rd., Galway
REP. OF IRELAND
(VAT# IE 8242533I)

ORDER #	SHIP DATE	CUST #	PO NUMBER	SHIP VIA	TERMS
17792	3/16/98	M02220	7517	UPS - EXPRESS "cc"	NET 30 DAYS

ITEM	QUANTITY	UNIT	DESCRIPTION	S	UNIT PRICE	AMOUNT
3010	500	EA	Y connector with 2 female		0.22500 EA	112.50
	LOT #:Q4287		CPN: CC97012 Rev.0			
			HANDLING FEE			25.00
			ORDER COMPLETE			

RECEIVED 20 MAR 1998

IENTS:
THANK YOU FOR YOUR ORDER!
SEE OTHER SIDE FOR RETURN GOODS POLICY

TOTAL ▶ 137.50

Exhibit 36

QOSINA

150-Q EXECUTIVE DRIVE
EDGEWOOD, NY 11717-8329
TEL: (516) 242-3000
FAX: (516) 242-3230
info@qosina.com www.qosina.com

STATEMENT

DATE
04/01/98

ACCOUNT NUMBER
M02220

RECEIVED - 6 APR 1998

MEDNOVA LTD.
Unit 3, IDA Enterprise Park
Tuam Rd. Galway
Rep. of Ireland

REFERENCE	DATE	CODE	DESCRIPTION	AMOUNT
28685	03/16/98	IN	7517	137.50

CODE: BF-BALANCE FORWARD, IT-INTEREST CHARGE, DS-DISCOUNT, IN-INVOICE, DR-DEBIT MEMO, CR-CREDIT MEMO, CA-CASH PAYMENT

PLEASE PAY ▶ 137.50

Current	Over 30	Over 60	Over 90 Days
137.50	0.00	0.00	0.00

Montefiore Hospital, Bronx NY
March 14th, 1998

1st In Vitro Plaque Filtration Test

Ref: Ohki Model

Comments: The model was set up in accordance with the outline in Dr. Ohki's paper. A surgically explanted plaque was sutured into a PTFE surgical graft with a small aperture almost but not quite closed off by suturing. Distal vasculature was represented by a 5mm PTFE graft sutured to the system. The whole assembly was mounted in a water bath that was not temperature controlled and with access to the lesion by way of Teflon catheters, without any tortuousity. Endoscopic and fluoroscopic imaging was available. A filter was set up distally to capture any material not retained by the MedNova filter. A 6mm NeuroShield was used to study feasibility.

- **Set Up:**
  - Loading OK.
  - Alignment of metal tube to Pkg. It needs to be corrected.
  - Push pull loading worked fine.
  - Pulled back too much with filter outside pod.
  - Second system was opened.
  - Leak at hub.
  - Loaded fine.
  - Flushed around filter successfully.
  - Wires
    - First 13/16 wire seemed to have poor wire movement.
    - Loaded up .014"
    - Caught up.
    - Noticed the Tuohy-Borst was closed.
    - Re loaded the 13/16.
    - It was notchy and gritty to load.
    - Wire moved distal/proximal.
    - Poor torque control.

- **Insertion & Crossing**
  - Tip transition step is not satisfactory.
  - G.R. felt the crossing to be difficult.
  - Torquing the delivery catheter helped to steer the system.
  - Deployed satisfactorily under fluoroscopic image. P.G.
  - Some difficulty with maintaining position of filter during the removal of the loading catheter.

- Initially the nitinol element opened and was visible fluoroscopically.
- There was some clear flow alongside the filter.
- Dr. Ohki intervened and manipulated the distal vessel, which corrected the flow scenario.
- The dilation balloon was loaded and the lesion angioplastied.
- There was visual evidence of embolic material being released.
- The stent system was then advanced but hung up with the endoscope.
- The endoscope was removed and a second stent inserted.
- Again some difficulty in holding the filter position was seen.
- The wall stent was deployed and visibly released debris.
- The stent delivery system was removed.
- A 6mm post dilation balloon was inserted and used to provide an improved angiographic result.
- It was then removed.
- The retrieval system was then loaded and advanced into the stent to its distal end.
- The filter and wire were then pulled back into the catheter and it was removed.
- There was no aspiration.
- The filter was removed and cut open.
- A number of large particles were visible and photographed by Dr. Ohki.
- The end filter of the model was removed and evaluated.
- Three particles, the largest being ~ 0.08 mm, were retrieved.
- Photographs were taken by Dr. Ohki and will be forwarded after development at Montefiore.

Comments:

- The system performed its primary function, was deployed and did retrieve embolic material.

- Improvements are needed to address system performance in the following areas:

  - Prep needs to be simplified.
  - Transition from pod to wire/polyimide needs to be improved.
  - Guide wire movement needs improvement.
  - The filter needs to accommodate vessel size variances.

18/3/98

To: M. Claffey, File, S. Horan, J. O'Shaughnessy, D. Vale, S. Eighan, P. Gilson, P. Maher, C. Taylor

From: Eamon Brady

Date: 24/03/98

Subject: Design Review Minutes 23/3/98

A meeting was held on 23 March 98 to discuss the design changes required as a result of the Ohki trial in NY a week ago. In attendance were P. Gilson, P. Maher, S. Horan, D. Vale, S. Eighan, M. Claffey, J. O'Shaughnessy, C. Taylor & E. Brady.

The meeting started with Paul outlining the key areas that needed to be focused on as a result of the trial as follows:

1. User Friendliness: The system in its Ohki configuration is not very user friendly. This is partly due to the difficulty in positioning the balloon in the correct position in the pod. If the position is incorrectly set the user is left with either a bad transition or the filter is partially deployed. The Touhy Borst leaked during flushing.
2. Tip Transition: The tip transition was deemed to be unacceptable by Dr Rubin. The tip transition needs to have a smooth profile with no hang up points to facilitate smooth crossing. Ideally it should not significantly compromise the tip trackability.
3. Balloon Sizing: The diameter of the filter used in the Ohki model was 6.2mm and this was deployed in a 5.0mm "vessel". This level of mismatch caused the filter to crease slightly.
4. Wire Movement: This issue is directly attributable to the use of the polyimide. During the Takao Ohki trial a 0.014" wire could not be loaded into the polyimide and when a wire was loaded the movement was very poor.

The design changes which have been under discussion over the last week were then discussed. The following action items were agreed.

- The loading tool is in contact with the tray during prep. Dave will modify the tray. This change will not be in place for the next trial.
- An "olive" component is required to provide a smooth transition between the polyimide and pod. This olive will be designed to have a smooth distal transition and will be such as to allow easy positioning of the filter in the pod. Ideally the olive will be a soft material like PEBAX. Padraig is dealing with this design change.
- The Touhy Borst needs to be leak proof. Susan has already implemented controls to deal with this issue.
- A series of alternative balloon designs are being prototyped by Steven. All of these designs will be assessed in terms of their crease performance in vessels of smaller size.

Exhibit 38

- The new filter designs will be made available in the size ranges outlined in the Table. Stephen will continue to be responsible for balloon dipping.

Labelling	Size
6.0	5.7 to 6.2
5.5	5.2 to 5.7
5.0	4.7 to 5.2
4.5	4.2 to 4.7
4.0	3.7 to 4.2

- The delivery catheter shaft OD will be increased to accommodate the internal pusher for deployment. Padraig has sample spring components for this on order. Extruded tubing will also be ordered as a backup option. Dave will take responsibility for implementing these changes.
- Chas suggested that we attempt to get as many distal holes into the filter as possible. There are currently over 100 holes. Padraig will look at this.
- It was agreed that we would change to the "floating on the wire" system. This design involves mounting the filter and olive on a short length of polyimide which is mounted on the wire but can move on the wire between two stops. This design has the major advantage of facilitating wire movement independent of the filter element. This was the most important decision taken at the meeting and the following were the reasons why the decision was taken.
    1. Using a "floating on the wire" system eliminates the wire movement issues
    2. The system becomes compatible with 0.014" balloon catheters and stent delivery systems. Suppliers of these products are moving in the direction of 0.014" delivery systems.
    3. The wire can be torqued independently of the filter or delivery catheter with no significant frictional losses.
    4. The filter position can be maintained during the exchange of catheters
    5. The cost of the product may be reduced significantly.

The main down side to this decision was that the customer looses choice of wire. The design of this system involves the design of the filter assembly and the design of the guidewire. The filter assembly design will be developed by Padraig and Susan.

It was agreed that prototype systems incorporating these design changes will be prepared for evaluation in the Ohki model by Thursday 2nd April 98.

Eamon Brady

TO: Mairsil Claffey
Eamonn Brady
Paul Gilson
CC: Team
From: Shivaun O'Rourke

Date: 6/3/98.

Subject: Screening Validations.

The status of the screening validations as of this date are as follows:

PTFE shrink 01- Signed off.
Nitinol forming 04 -Signed off.
Bond nitinol and Marker Band 05- Signed off.

Touhy Borst 03 -Await Mairsil & Eamonn's approval.
Shrinkage of PTFE onto Grit blasted Hypotubing 07-Await Mairsil & Eamon's approval.
Bonding of PTFE/Grit blasted hypotubing onto Perspex rod-08-Await Mairsil & Eamon's approval.

Dipping & Drying 06-Await stephen to finalise the process to update protocol.
Shrinkage of PTFE to Monel wire for formation of loading pod 09-Await test results from padraig to identify the size of Monel wire to be used in the validation.
Delivery Catheter Pod Shrinkage 010-Await for engineering results from Dave .
Heat Sealer Validation 011-Heating element to be assessed.
Balloon Bonding screening 012 -Await Balloons.
Lloyd tensile tester Validation 013-Protocol to be written.

Shivaun O'Rourke

S/ Shivaun O'Rourke

Exhibit 39

PAYNE PLASTICS

C.B. PAYNE (PLASTICS) LIMITED
Inchbrook Trading Estate.
Woodchester, Stroud, Glos. GL5 5EY
Tel: 01453 835301 Fax: 01453 835151

INVOICE

VAT No. 276 1581 42

INVOICE ADDRESS	DELIVERY ADDRESS (IF DIFFERENT)
1067 MEDNOVA LTD UNIT 3.IDA BUSINESS PARK TUAM ROAD GALWAY REPUBLIC OF IRELAND	

DATE – TAX POINT	YOUR ORDER No.	OUR REF. No.	INVOICE No. 13879
17.3.98	7475	B2850	

QUANTITY	DESCRIPTION	UNIT PRICE	VAT RATE	VALUE
	MACHINED PERSPEX ROD DRG.CA97-001 MODIFIED			
19	DELIVERY NOTE 17942 2.3.98	0.40	0.00%	7.60
1	PACKING & POSTAGE	2.50	0.00%	2.50
263	DELIVERY NOTE 17984 17.3.98	0.40	0.00%	105.20
1	TOOLING	25.00	0.00%	25.00
1	DELIVERY VIA TNT INTERNATIONAL	30.00	0.00%	30.00

RECEIVED - 3 APR 1998

TOTAL GOODS	170.30
VAT	0.00
TOTAL DUE £	170.30

TERMS: NETT BY THE 30th OF THE MONTH FOLLOWING THE MONTH OF INVOICE

E. & O.E.

3. INTEREST WILL BE CHARGED ON ALL OVERDUE INVOICES AT THE RATE OF 5% /MONTH

Exhibit 40

MEDNOVA LTD..	Doc. No. SA98 003 Revision: 02	Page 1 of 2
TITLE:	Laser Machined Coated Core	
	Effective Date: 18 MAR 1998 Issue Date: 18 MAR 1998	

1.0 Physical properties

- Description: Coated acrylic core with laser machined holes at each end as per attachments 1 and 2.
- Dimensions: Reference Attachment 1 and 2
- Colour: White
- Shape: Cylindrical with conical ends
- Surface Character: Product to be supplied free of surface blemishes, char marks, dirt or contamination.

2.0 Chemical Properties

Not Applicable

3.0 Vendor Requirement

3.1 The vendor must supply a certificate of conformity for this product stating:
- The product supplied against this vendor code complies with agreed specifications or
- The product meets the requirements outlined in this specification.
- MedNovas Purchase Order reference
- Total quantity shipped

3.2 All deliveries must clearly reference the assigned MedNova lot number.

3.3 All goods to be packed as per packaging procedure PP98 001

4.0 Vendor

4.1 For vendor details see Approved Vendor Listing (Ref. QP97 009)

5.0 Vendor Code

SA98 003

6.0 References

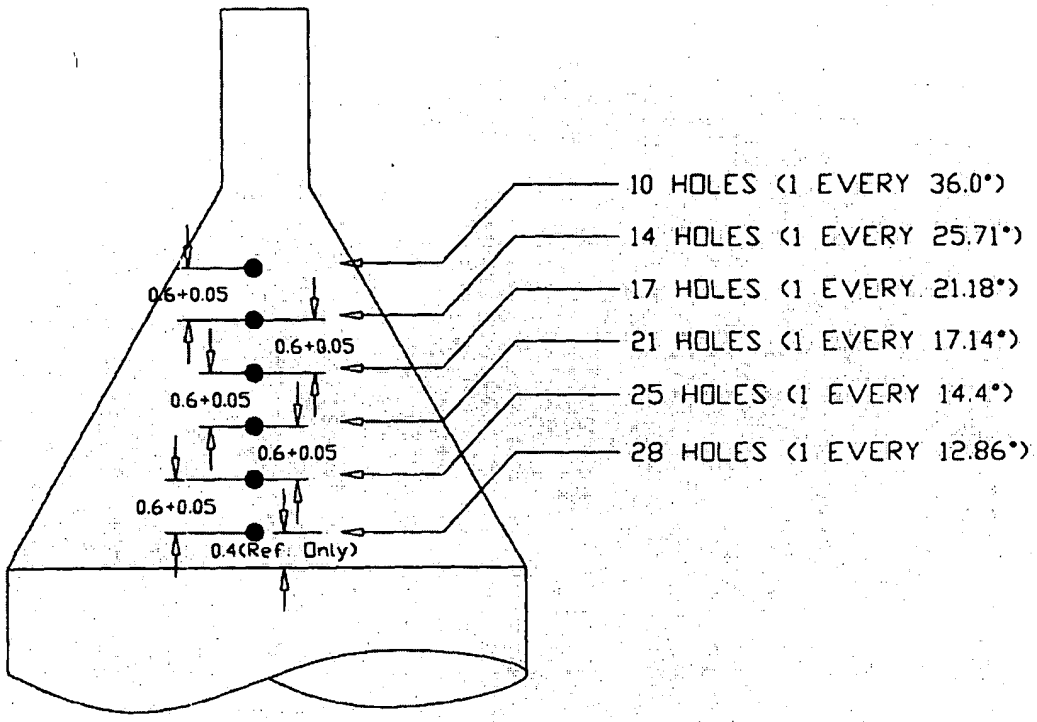
Approved Vendor Listing	-	QP97 009
Packaging Procedure	-	PP98 001

Exhibit 41

Approvals		Date
Originator:	Padraig Maher	18/3/98
Research and Development Manager:	Eamon Brady	18-03-98
Quality and Regulatory Affairs Manager:	Hazel Cleffey	18/3/98

LOCATIONS FOR A TOTAL OF 115 SMALL HOLES TO BE MACHINED INTO THE CONICAL END.

HOLE Ø 0.2-0.02
HOLE DEPTH 0.3±0.05

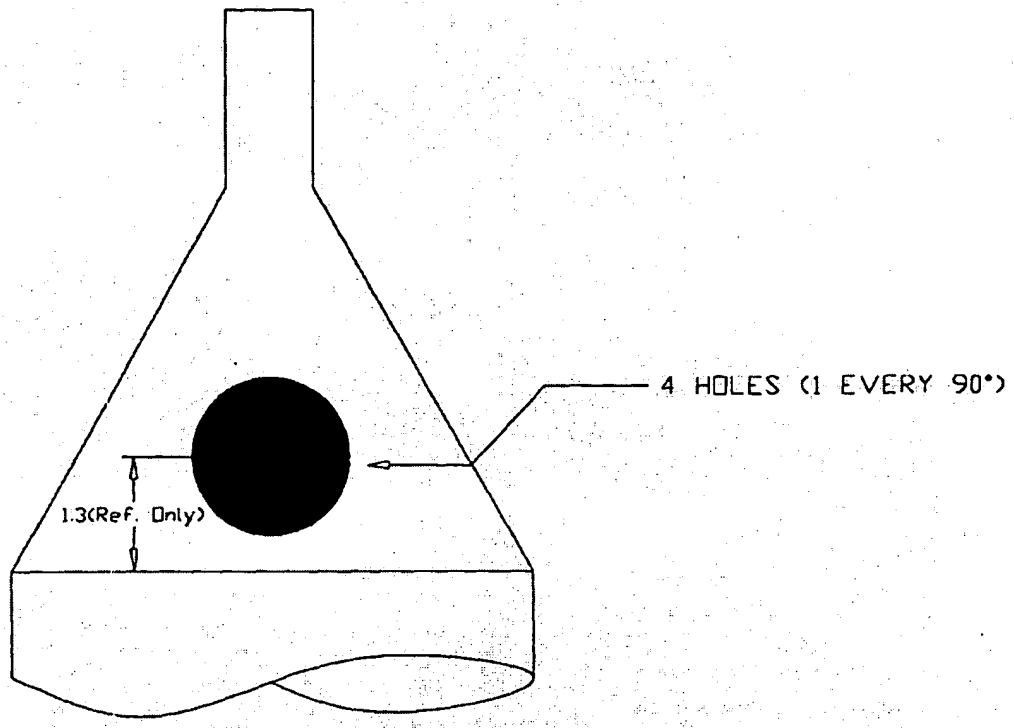


END OF THE COMPONENT MARKED BY THE PRESENCE OF THE BLACK O-RING

SA98 003 Rev. 02	
Laser Machined Core	
DATE: 18/03/98	DRAUGHTED BY: P MAHER
All Dimensions in mm	Attachment 1.0

LOCATION OF THE 4 LARGE HOLES TO BE MACHINED IN THE OPPOSITE CONICAL END.

HOLE Ø 1.8+0.1
HOLE DEPTH 0.3±0.05



SA98 003 Rev. 02	
Laser Machined Core	
DATE: 18/03/98	DRAUGHTED BY: P MAHER
All Dimensions in mm	Attachment 2.0

EDNOVA LTD.	Doc. No.	Form QP97 012.1	Page 1 of 1
	Revision:	00	
TITLE:	Purchase Order		

MedNova Ltd
Unit 3, IDA Enterprise Park,
Tuam Road,
Galway. Rep. of Ireland.
Tel: Int +353 (0)91 758288
Fax: +353 (0)91 758272

PURCHASE ORDER

The following number must appear on all related correspondence, shipping papers, and invoices:
P.O. NUMBER: 7550

To: MARK GOEMER
SPECTRAlytics Inc.
7456 West 78th Street
Minneapolis MN 55439

Ship To: PADRAIG MAHER
Above Address

P.O. DATE	REQUISITIONER	SHIP VIA	F.O.B. POINT	TERMS
18/3/98	P. Maher	FED-EX	C.I.F.	Standard

QTY	UNIT	DESCRIPTION	UNIT PRICE	TOTAL
230	1	Laser Machined Coated Cone as per MedNova Specification SA 98003 Rev. 02. Date:- 18/3/98 Parts must maintain lot history traceability with MedNova lot #'s. Vendor lot # & Certificate of Conformance Required.	$18.75	$4312.5

SUBTOTAL	$4312.5
VAT	0%
SHIPPING & HANDLIN	
OTHER	
TOTAL	

VAT: IE 8242533I
VAT EXEMPT NO: 11 / 03235 / 1098

1. Please send two copies of your invoice
2. Enter this order in accordance with the prices, terms, delivery method, and specifications listed above.
3. Please notify us immediately if you are unable to ship as specified.

Eamon Boyle 18-3-98
Authorised by Date

Exhibit 42

SPECTRAlytics
Specializing in Laser Solutions
7456 West 78th Street, Minneapolis, MN 55439
Phone (612) 942-5853
Fax (612) 942-5682

* * * INVOICE * * *

PAGE NO. 1
INVOICE NO. 4820
INVOICE DATE 03/30/98

RECEIVED - 6 APR 1998

SOLD TO:

MEDNOVA LTD.
UNIT 3, IDA ENTERPRISE PARK
TUAM ROAD, GALWAY
REPUBLIC OF IRELAND,

ATTN: Accounts Payable

SHIP TO:

MEDNOVA LTD.
UNIT 3, IDA ENTERPRISE PARK
TUAM ROAD, GALWAY
REPUBLIC OF IRELAND,

CUSTOMER PO	TERMS	SHIP VIA	SALESPERSON
550	N10	FED EX - INTL	MARK GOEMER

LINE	QUANTITY	DESCRIPTION	ORDER	UNIT PRICE	AMOUNT
1	229	98003 REV 02 LASER DRILL COATED CORE	980371	18.750000	4,293.75

PACKING LIST 7258 SHIP DATE 03/30/98 QUANTITY 229

SUBTOTAL	4,293.75
PREPAID	0.00
FREIGHT	0.00
MISC. CHARGES	0.00
SALES TAX	0.00
BALANCE DUE	4,293.75

Authorised by Date

Exhibit 43

MEDNOVA LTD..	Doc. No. Form QP97 001.2 Revision: 02	Page 1 of 1
TITLE:	Change Request Form	

Document requiring changes

Doc. No.: SA98003 Title: Laser Machined Coated Core Version: 02

Required Changes:

Tolerance on hole Ø.

Ø1·85 ± 0·16 mm

Ø0.2 ± 0·04 mm

Justification for Changes:

Tolerances that SPECTRAlytics have informed us that they can hold.

Training Required: No

Re-validation Required: No **Screening Affected:** No

Re-screening Required: No

Comments:

Change Requested By

Print: PADRAIG MAHER Sign: Padraig Maher Date: 26/3/98

QA Engineer

Print: J. Mayer Sign: J. Mayer Date: 26/3/98

Exhibit 44

MEDNOVA LTD..	Doc. No. SA98 003 Revision: 03	Page 1 of 2
TITLE:	Laser Machined Coated Core	
	Effective Date: 26 MAR 1998 Issue Date: 26 MAR 1998	

1.0 Physical properties

- Description: Coated acrylic core with laser machined holes at each end as per attachments 1 and 2.
- Dimensions: Reference Attachment 1 and 2
- Colour: White
- Shape: Cylindrical with conical ends
- Surface Character: Product to be supplied free of surface blemishes, char marks, dirt or contamination.

2.0 Chemical Properties

Not Applicable

3.0 Vendor Requirement

3.1 The vendor must supply a certificate of conformity for this product stating:
- The product supplied against this vendor code complies with agreed specifications or
- The product meets the requirements outlined in this specification.
- MedNovas Purchase Order reference
- Total quantity shipped

3.2 All deliveries must clearly reference the assigned MedNova lot number.

3.3 All goods to be packed as per packaging procedure PP98 001

4.0 Vendor

4.1 For vendor details see Approved Vendor Listing (Ref. QP97 009)

5.0 Vendor Code

SA98 003

6.0 References

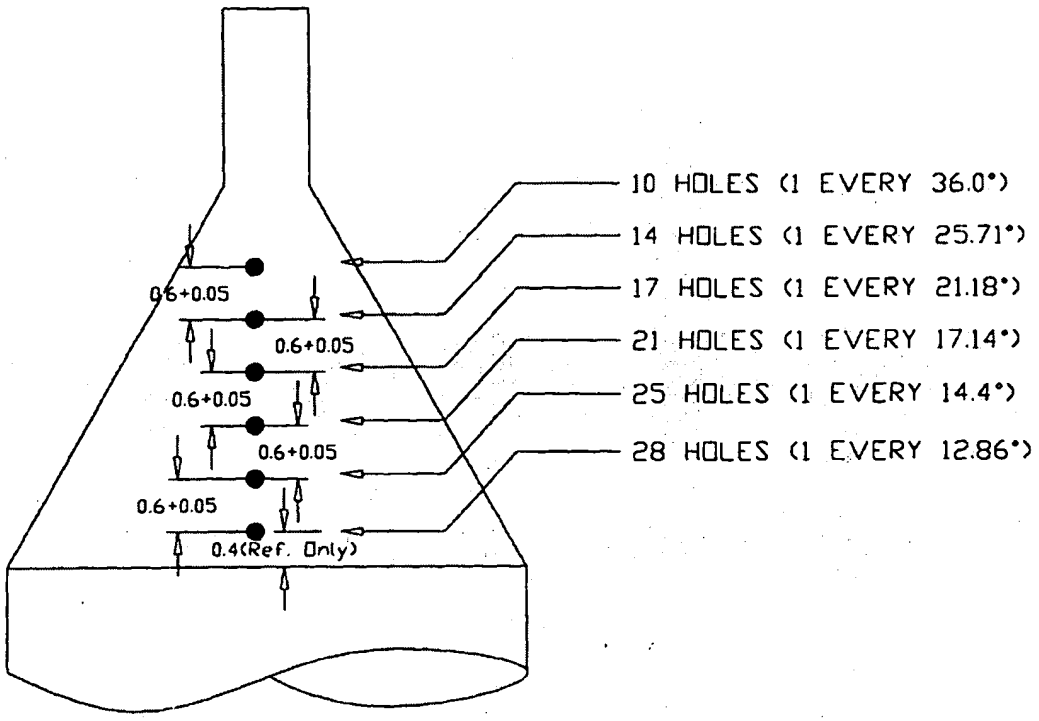
Approved Vendor Listing - QP97 009
Packaging Procedure - PP98 001

Exhibit 45

Approvals		Date
Originator:	Padraig Mahr	26/3/98
Research and Development Manager:	Emma Brady	26-3-98
Quality and Regulatory Affairs Manager:	Mary Copley	26/3/98

LOCATIONS FOR A TOTAL OF 115 SMALL HOLES TO BE MACHINED INTO THE CONICAL END.

HOLE Ø 0.2±0.04
HOLE DEPTH 0.3±0.05

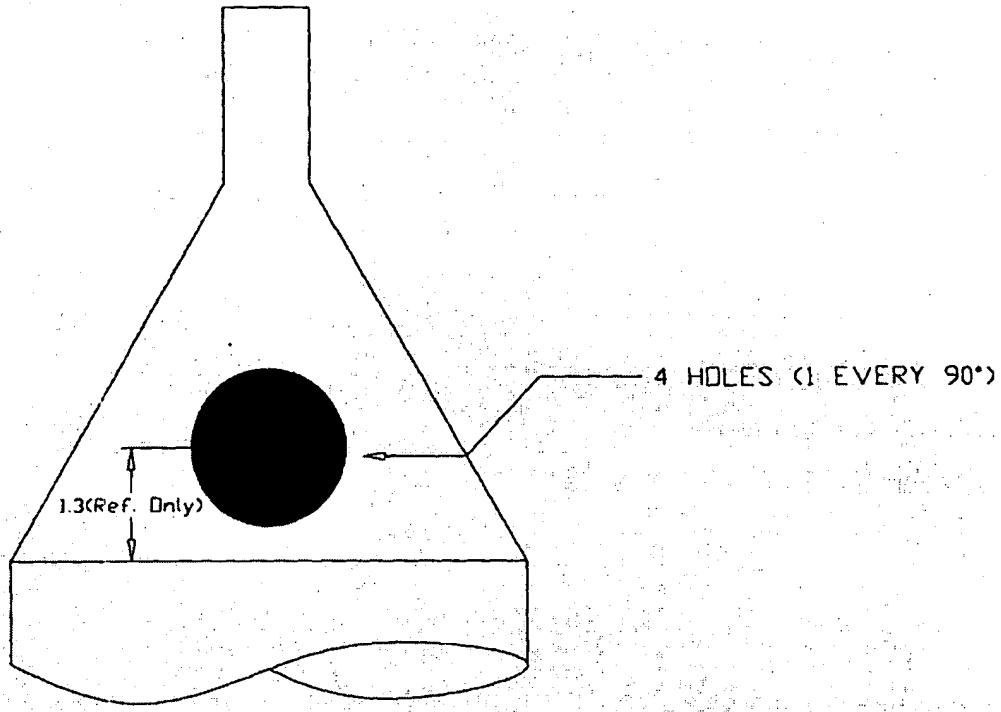


END OF THE COMPONENT MARKED BY THE PRESENCE OF THE BLACK O-RING

SA98 003 Rev. 03	
Laser Machined Core	
DATE: 26/03/98	DRAUGHTED BY: P MAHER
All Dimensions in mm	Attachment 1.0

LOCATION OF THE 4 LARGE HOLES TO BE MACHINED IN THE OPPOSITE CONICAL END.

HOLE Ø 1.85±0.16
HOLE DEPTH 0.3±0.05



SA98 003 Rev. 03	
Laser Machined Core	
DATE: 26/03/98	DRAUGHTED BY: P MAHER
All Dimensions in mm	Attachment 2.0

MEDNOVA LTD..	Doc. No. Form QP97 001.2 Revision: 02	Page 1 of 1
TITLE:	**Change Request Form**	

Document requiring changes

Doc. No.: SA98003 **Title:**laser machined coated core 6mm **Version:**03

Required Changes:

Make SA98003 Obsolete

Justification for Changes:
SA 98003 is a routing for coated core (6mm) This has now been replaced by a range of three new hole designs for the coated core.

Training Required:N/A

Re-validation Required: N/A **Screening Affected:** N/A

Re-screening Required: N/A

Comments: N/A

Change Requested By

Print:Susan Eighan **Sign:** Susan Eighan **Date: 24/08/98**

QA Engineer

Print: JHAGER **Sign:** JHager **Date:** 25/8/98

MEDNOVA LTD..	Doc. No. Form QP97 001.3 Revision: 00	Page 1 of 1
TITLE:	Document Receipt Form	

Document Number	Document Title	Revision Number	Received By	Department
~~SA98003~~	~~Laser Machined Core~~	~~00~~	EG	R&D
SA98003	Laser Machined Core	01	EG	R&D

→ Document Superseded.

NOVA LTD.	Doc. No. Form QP97 012.1 Revision: 00	Page 1 of 1
TLE:	Purchase Order	

MedNova Ltd
Unit 3, IDA Enterprise Park,
Tuam Road,
Galway. Rep. of Ireland.
Tel: Int +353 (0)91 758288
Fax: +353 (0)91 758272

PURCHASE ORDER

Rec.

The following number must appear on all related correspondence, shipping papers, and invoices:
P.O. NUMBER: 7549.

To: John McCarthy
Murphy Engineers
01-4500608

Ship To: Susan Eighan
Above Address

P.O. DATE	REQUISITIONER	SHIP VIA	F.O.B. POINT	TERMS
18/3/98.	S. Eighan.	Express.	C.I.F.	Std.

QTY	UNIT	DESCRIPTION	UNIT PRICE	TOTAL
5	1.	UV adhesive 3301	£33.58	167.9

SUBTOTAL	£167.9
VAT	0%
SHIPPING & HANDLIN	~
OTHER	~
TOTAL	£167.9

VAT: IE 8242533I
VAT EXEMPT NO: 11 / 03235 / 1098

1. Please send two copies of your invoice
2. Enter this order in accordance with the prices, terms, delivery method, and specifications listed above.
3. Please notify us immediately if you are unable to ship as specified.

Susan Eighan 18/3/98.
Authorised by Date

Exhibit 46

ADVICE NOTE LD 33

Murphy Engineers Limited

Industrial Engineering Distributors
John F. Kennedy Avenue, Dublin 12.
Tel: 450 0088 / 450 1819 / 450 2072 Fax: 450 0602

KILKENNY SALES OFFICE:
HEBRON ROAD
KILKENNY.
Tel; (056) 62852. Fax: (056) 61567

Invoice To:
M. NEONova LTD,
Unit 3, IDA Enterprise Park, Tuam Rd, Galway.

Deliver To:
M.

Date 6.4.98 A/C No. Order No. 7549

Part No.	Description	Unit	Quantity	Price	Per
	x 25ml Syringes 3301 Boxte		5		
	Un Orbome.				
	Attn, Ms. Susan Eignan.				
	Conformance Certificates Enclosed.				
	Express Post		-		

ALL GOODS ARE SUPPLIED SUBJECT TO OUR CONDITIONS OF SALE PRINTED OVERLEAF.
V.A.T. No. 8 Y 88267 N

Received by .....

VAT: IE 8242533I
VAT EXEMPT NO: 11/03235/1098

1. Please send two copies of your invoice
2. Enter this order in accordance with the prices, terms, delivery method, and specifications listed above.
3. Please notify us immediately if you are unable to ship as specified.

OTHER
TOTAL £1679

Authorised by [signature] 6/4/98

Exhibit 47

PROJECT TEAM MEETING REVIEWS

Meeting Date: ...18-03-1998

Attendees: SOR, SH, PM, KR, JH, SE, MC & EB

Copy: File, CT,DV, PG

Last week you only hit 30% of your targets. Lets strive for 100%.

Next weeks key goals	Last weeks achievements	General Responsibility
Keith Ryan		
• Define pouch seal process window • Finish load mech sterility/bio build • Pod screening of overlap joint complete • Compare MedNova seals to suppliers • Sort out monel wire/PTFE issues • Build test product for Padraig	• Sorted out PTFE rig issues • Built parts for screening	PTFE shrink development work
Shivaun O Rourke		
• **Approve pod shrink protocol** • Approve pouch seal protocol (X2) • Update second pod shrink validation • Write software validation protocol • Polyolefin validation started • Overlap testing complete	• Built master plan into validn. Procedure • Pouch seal validation signed off	Responsible for test development and validation.
Susan Eighan		
• **Resolve Teflon shrink process issues** • Finalise core removal process • Train Contech staff • UV bonding studies	• Move core removal to Contech • Put process controls in place for Nitinol cracking issue • Built filter samples for Paul	-Catheter manufacturing line set up and operation in Contech, Nitinol forming & balloon bond
Padraig Maher		
• Retest new loading mech design • **Revise spec & order sterility/bio pieces** • Evaluate deployment & retrieval force • Define balloon wrap method	• Wrote up nitinol test results	Core punching, core assembly and specifications
Jon Hager		
• **End of line routing approved** • Inspect loading mechanism • Inspect sterility product • Approve vendor listing • Train J. Mc Donagh on inspections • QA Inspections	• Compiled bio. Info from vendors • QA Inspections ongoing	-Vendor approval -Receiving goods system -Documentation -DMR Development
David Vale		
• **Pod engineering studies complete** • Approve package procedures • Order printed labels for bench testing	•	-Labelling -Retrieval catheter -Loading mechanism -Packaging
Steven Horan		
• Dip balloons for UV bonding trials • Reduce balloon wall thickness • Evaluate new SD • UV Build for Susan	• Analysed balloon dip data • Evaluate balloon strengths • Order cores from CP and US	Responsible for: -Balloon development
Chas Taylor		
• Labels/ IFU available for builds	• Ideally available 20/2/98 • Worst case available 3/3/98	Labelling, IFU

Exhibit 48

MEDNOVA LTD.	Doc. No. Form QP97 012.1 Revision: 00	Page 1 of 1
TITLE:	Purchase Order	

MedNova Ltd
Unit 3, IDA Enterprise Park,
Tuam Road,
Galway. Rep. of Ireland.
Tel: Int +353 (0)91 758288
Fax: +353 (0)91 758272

(R)

PURCHASE ORDER

Quotation Reference No. 980533

The following number must appear on all related correspondence, shipping papers, and invoices:
P.O. NUMBER: 7551

To: TERRY SMITH
ASHFIELD SPRINGS,
Wainbrook Rise, Nobleglenshire.

Ship To: PADRAIG MAHER
Above Address

P.O. DATE	REQUISITIONER	SHIP VIA	F.O.B. POINT	TERMS
19/3/98	P. Maher	Express	C.I.F.	Standard

QTY	UNIT	DESCRIPTION	UNIT PRICE	TOTAL
20	1	CLOSE COILED STAINLESS STEEL TENSION SPRING O.D. 0.058" ± 0.0005" x 1260mm ± 5mm long wire Ø 0.010" ± 0.0003"	£8	£160
20	1	O.D. 0.036" ± 0.0005" x 1430mm ± 5mm long wire Ø 0.007" ± 0.0003"	£8	£160
20	1	OD. 0.056" ± 0.0005" x 1260mm ± 5mm long wire Ø 0.010" ± 0.0003"	£8	£160
20	1	O.D. 0.034" ± 0.0005" x 1430mm ± 5mm long wire Ø 0.006" ± 0.0003"	£8	£160
20	1	O.D. 0.060" ± 0.0005" x 1260mm ± 5mm long wire Ø 0.0116" ± 0.0003"	£8	£160
		Vendor Lot # & Certificate of Conformance required.		
			SUBTOTAL	£800
			VAT	0%
			SHIPPING & HANDLING	-
			OTHER	
			TOTAL	

VAT: IE 8242533I
VAT EXEMPT NO: 11 / 03235 / 1098

- Please send two copies of your invoice
- Enter this order in accordance with the prices, terms, delivery method, and specifications listed above.
- Please notify us immediately if you are unable to ship as specified.

Eamon Boyle 19-3-98
Authorised by Date

Exhibit 49

MedNova Ltd
Unit 3, IDA Enterprise Park,
Tuam Road,
Galway. Rep. of Ireland.
Tel: Int +353 (0)91 758288
Fax: +353 (0)91 758272

PURCHASE ORDER

The following number must appear on all related correspondence, shipping papers, and invoices:
P.O. NUMBER: 7517

To:	Ship To:
QOSINA (DENISE HERNANDEZ)	Above Address

P.O. DATE	REQUISITIONER	SHIP VIA	F.O.B. POINT	TERMS
12-03-98	DAVID VALE	—	C.I.F.	STD

QTY	UNIT	DESCRIPTION	UNIT PRICE	TOTAL
500	—	Y-CONNECTOR AS PER MEDNOVA SPEC CC97012 REV Ø (QOSINA PART NO: 83010)	—	$112.50

SUBTOTAL	$112.50
VAT	—
SHIPPING & HANDLIN	
OTHER	
TOTAL	

VAT: IE 8242533I
VAT EXEMPT NO: 11/03235/1098

1. Please send two copies of your invoice
2. Enter this order in accordance with the prices, terms, delivery method, and specifications listed above.
3. Please notify us immediately if you are unable to ship as specified.

D. Vale 12/3/98
Authorised by Date

Exhibit 51

MEDNOVA LTD..	Doc. No.	MP98 002	Page 1 of 4
	Revision:	01	
TITLE:	LOADING MECHANISM BONDING / LUBRICATING		
	Effective Date: 19 MAR 1998	Issue Date: 19 MAR 1998	

1.0 Purpose

This procedure outlines the method used when bonding the finished PTFE/Grit Blasted Tube assembly to the Perspex Rod and applying lubrication.

2.0 Scope

The adhesive bonding of 2 sub assemblies to form a completed loading mechanism.

3.0 Responsibility

3.1 It is the responsibility of the manufacturing supervisor to ensure that adequate resources are in place for all relative manufacturing operations and that production is completed in accordance with the manufacturing procedure.

3.2 It is the responsibility of the designated engineer to ensure that adequate initial training is given to all production personnel including the production supervisor and that all current procedures are in effect so that subsequent training can be performed in house by the production supervisor.

4.0 Equipment

- Adhesive dispensing Station
- Tube/PTFE Holding tray.
- Loading Mechanism Holding Tray
- Loading Mechanism Bonding Fixture
- 0.075" Pin
- Plastic beaker

5.0 Set Up

5.1 Connect up the air supply to the adhesive dispensing station.

5.2 Place a cap on the tip of a 3cc dispensing barrel.

5.3 Wear protective latex glove when using the adhesive and avoid direct inhalation.

5.4 Half fill the barrel with 4061adhesive ensuring not to let any adhesive dribble along the sides of the barrel as it will cause the piston to adhere to the barrel which will prevent dispensing. Sit the piston into the barrel and fit the vacuum line to the top of the barrel. Switch on the dispensing unit and turn the vacuum on.

5.5 Remove the cap from the top of the barrel and place the dispensing tip in its place.

5.6 Put the dispensing unit into auto mode. For nominal process conditions set the dispensing time to setting 2 and the pressure to 1 bar. Adjust the vacuum to a suitable level, which will prevent dribbling of the adhesive out of the tip, but which is not strong enough to allow air to be drawn through the tip of the barrel.

5.7 Before commencing the bonding process, the operator completes the process record log ref. Form MP98002.1. This process history details the test number, date and time the test was carried out, the manufacturing lot number and quantity, and the adhesive lot number and expiry date.

5.8 The test to be carried out entails using the foot pedal to dispense some drops into the circles on the lot history record sheet. The drop of adhesive should extend to or beyond the circumference of the inner circle and to or within the circumference of the larger circle.

5.9 If the first five drops are within the above specification the accept column shall be ticked and the lot history record will be signed as completed by the operator. If the first five drops are not within the above specification then the reject column is ticked and the corrective action is detailed in the detail column of the form. This process is continued adding any adjustments made in the comments column until the drops are found to be within the specification. The lot history record can then be signed as completed by the operator.

5.10 The Process Record Log ref. Form MP98002.1 will be kept at the manufacturing site and will be reviewed by Quality Assurance on a regular basis.

6.0 Procedure

6.1 Place the tube/PTFE assembly firmly into the stepped hole in the Perspex component ensuring that the tube has reached the bottom of the recess and place it into the loading mechanism bonding fixture (Fig 1. Below)

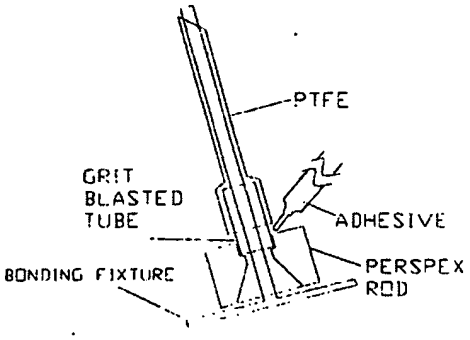


Fig 1.

6.2 Dispense 1 drop of adhesive just above where the perspex and tube meet spreading the glue around the edge of the contact area using the nib of the adhesive syringe. Leave the loading mechanism to dry before commencing the next operation.

6.3 Fill 2/3 of the plastic beaker with MED 361 Silicone Fluid (this is to be kept full enough to ensure that 10mm of the 0.075" pin will be covered while completing the lot.

6.4 Place the 0.075" pin 10mm into the fluid and remove it vertically. Gently swab the bottom of the pin to remove the drop which has accumulated.

6.5 Still holding the 0.075" pin vertically, slowly slide it in the bottom of the Perspex rod turning it as you do so at least 360° in the process. Shown in Fig 2.

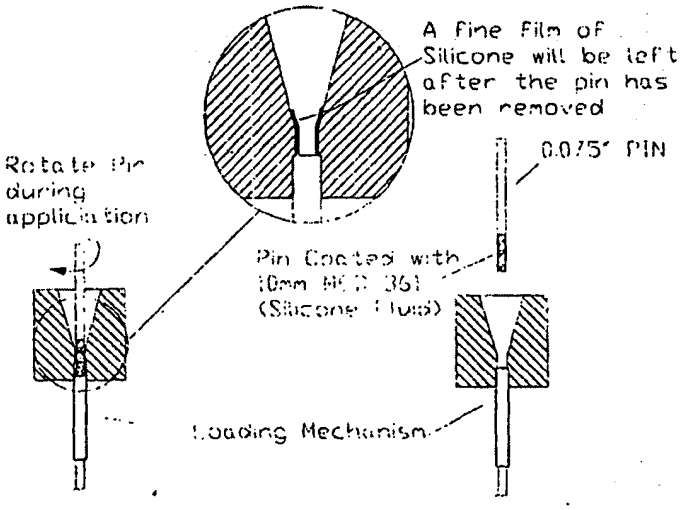


Fig 2.

6.6 Remove the 0.075" pin from the sub-assembly.

6.7 Repeat steps 6.4 to 6.6 until the lot is completed.

6.8 Replace the unused Silicone Fluid back into the bottle container.

6.9 Place the finished loading mechanism into the loading mechanism storage rack.

6.10 All completed Lots are to be stored in the designated storage bin.

6.11 Complete the Lot History Record

7.0 References

- Form MP98002.1 - PROCESS RECORD LOG - Tube / Perspex Bonding

Approvals		Date
Originator:	Keith Ryan	6/3/98
Quality and Regulatory Affairs Manager:	Mark Chaffey	11/3/98
Research and Development Manager:	Ciaran Brady	19-3-98

MEDNOVA LTD..	Doc. No. Revision:	Form QP97 001.2 02	Page 1 of 1
TITLE:	Change Request Form		

Document requiring changes LEADING MECHANISM

Doc. No.: MP9S 002 Title: BONDING - LUBRICATING Version: C1

Required Changes:

6.4 O. DELETE "LEADING-MECH BONDING FIXTURE"

- Change 0.0745" PIN to "LUBRICATION APPLICATION PIN

6.0 DELETE FIG 1. AND "PLACE INTO .. FIXTURE."

Justification for Changes:

- BONDING FIXTURE NOT USED
- 0.0745" PIN USED AS WELL AS OTHER SIZES

Training Required: N/A

Re-validation Required: N/A Screening Affected: N/A

Re-screening Required: N/A

Comments:

Change Requested By

Print: Susan Ligaj Sign: Susan Ligaj Date: 2/15/95

QA Engineer

Print: [illegible] Sign: [illegible] Date: [illegible]

MEDNOVA LTD..	Doc. No. CC97 007 Revision: 03	Page 1 of 2
TITLE:	**6mm Soluble Core (3)**	
	Effective Date: 20 MAR 1998 Issue Date: 20 MAR 1998	

1.0 Physical properties

- Description: Machined core, soluble in NaOH.
- Dimensions: Reference Attachment 1
- Colour: White
- Shape: Cylindrical with conical ends
- Material: Acrylic based soluble polymer

2.0 Chemical Properties

Dissolved by a 1% solution of NaOH.

3.0 Vendor Requirement

3.1 The vendor must supply a certificate of conformity for this product stating:
- The product supplied against this vendor code complies with agreed specifications or
- The product meets the requirements outlined in this specification.
- MedNovas Purchase Order reference
- Total quantity shipped

3.2 All deliveries must be clearly identified by a lot number.

3.3 All goods to be packed in a plastic bag inside a cardboard box

4.0 Vendor

4.1 For vendor details see Approved Vendor Listing (Ref. QP97 009)

5.0 Vendor Code

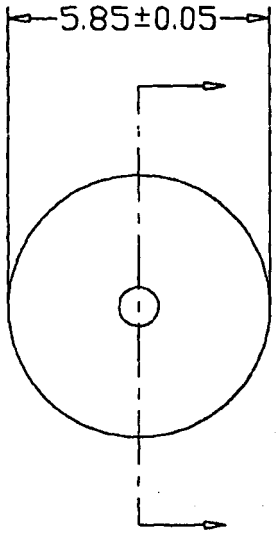
CC97 007

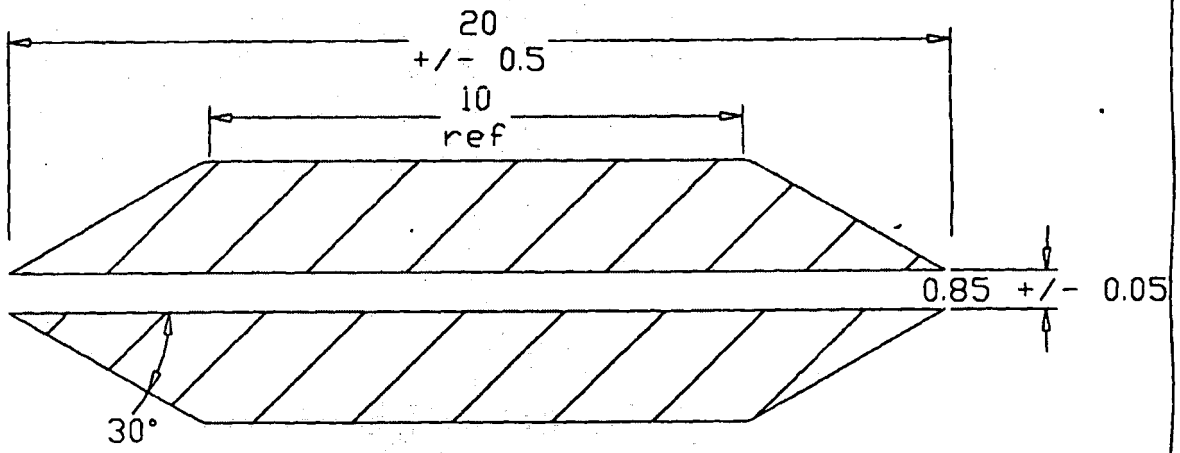
6.0 References

Approved Vendor Listing - QP97 009

Exhibit 53

Approvals		Date
Originator:	Steven Howe	18/3/98
Research and Development Manager:	Leanne Bayly	20-3-98
Quality and Regulatory Affairs Manager:	Maria Cleffey	20/3/98





ALL DIMENSIONS IN mm

COMPONENT SPECIFICATION DRAWING CC97007 Rev. 03	
6mm Soluble Core (3)	
	-
DATE: 19/03/98	DRAUGHTED BY: P MAHER
Attachment 1	

MEDNOVA LTD.	Doc. No. Revision:	**Form QP97 001.3** **00**	Page 1 of 1
TITLE:	**Document Receipt Form**		

Document Number	Document Title	Revision Number	Received By	Department
~~CC97007~~	~~Soluble Core (3)~~	~~01~~	~~EB~~	~~R&D~~
CC97007	Soluble Core (3)	02	EB	R&D

— Document Superseded

MEDNOVA LTD..	Doc. No. Revision:	Form QP97 001.2 02	Page 1 of 1
TITLE:	Change Request Form		

Document requiring changes

Doc. No.: CC97007 Title: 6mm Soluble Core (3) Version: 03

Required Changes:

Neck OBSolete

Justification for Changes:

CC97007 Specifies a Core which has a Centre hole machined along its length, this was necessary for Core assembly. Now it is possible to machine the Cores with the neck in place which ~~xxxx~~ 24/4/98 eliminates the need for Core assembly + also the need for having a hole along the length of the Core.

Training Required:

NIA

Re-validation Required: NIA **Screening Affected:** NIA

Re-screening Required: NIA.

Comments:

Change Requested By

Print: SUSAN EIGHAN Sign: Susan Eighan Date: 24/4/98.

QA Engineer

Print: SINEAD O'ROURKE Sign: Sinead O'Rourke Date: 24/5/98

MEDNOVA LTD..	Doc. No. CC97 010 Revision: 03	Page 1 of 2
TITLE:	5mm Soluble Core (6)	
	Effective Date: 20 MAR 1998 Issue Date: 20 MAR 1998	

1.0 Physical properties

- Description: Moulded core, soluble in NaOH.
- Dimensions: Reference Attachment 1
- Colour: White
- Shape: Cylindrical with conical ends
- Material: Acrylic based soluble polymer

2.0 Chemical Properties

Dissolved by a 1% solution of NaOH.

3.0 Vendor Requirement

3.1 The vendor must supply a certificate of conformity for this product stating:
- The product supplied against this vendor code complies with agreed specifications or
- The product meets the requirements outlined in this specification.
- MedNovas Purchase Order reference
- Total quantity shipped

3.2 All deliveries must be clearly identified by a lot number.

3.3 All goods to be packed in a plastic bag inside a cardboard box

4.0 Vendor

4.1 For vendor details see Approved Vendor Listing (Ref. QP97 009)

5.0 Vendor Code

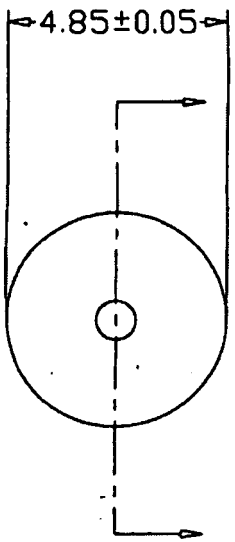
CC97 010

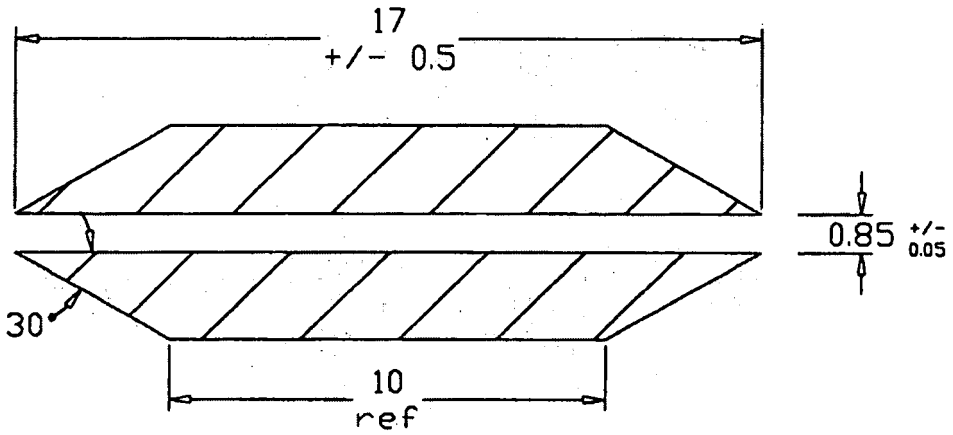
6.0 References

Approved Vendor Listing - QP97 009

Exhibit 54

Approvals		Date
Originator:	Steven Horan	18/3/98
Research and Development Manager:	Eamon Brady	20-3-98
Quality and Regulatory Affairs Manager:	Maire Cliffey	20/3/98





ALL DIMENSIONS IN mm

COMPONENT SPECIFICATION DRAWING CC97010 Rev. 03	
5mm Soluble Core (6)	
DATE: 19/03/98	DRAUGHTED BY: P MAHER
Attachment 1	

MEDNOVA LTD..	Doc. No. Revision:	**Form QP97 001.3** **00**	Page 1 of 1
TITLE:	**Document Receipt Form**		

Document Number	Document Title	Revision Number	Received By	Department
~~CC97010~~	~~Soluble Core (6)~~	~~00~~	~~EB~~	~~R&D~~
CC97010	Soluble Core (6)	01	EB	R&D
CC97010	Soluble Core (6)	02	EB	R&D

— Document Superseded

MEDNOVA LTD..	Doc. No. Form QP97 001.2 Revision: 02	Page 1 of 1
TITLE:	Change Request Form	

Document requiring changes

Doc. No.: CC97010 Title: 5mm Soluble Core (6) Version: 03

Required Changes:

Make Compared Spec obsolete.

Justification for Changes:

CC97010 Specifies a Soluble Core with no Neck + a Centre hole machined along its length. it is now possible to Machine Cores with Necks, therefore hollow Cores for Core assembly are no longer necessary.

Training Required:

N/A

Re-validation Required: N/A **Screening Affected:** N/A

Re-screening Required: N/A

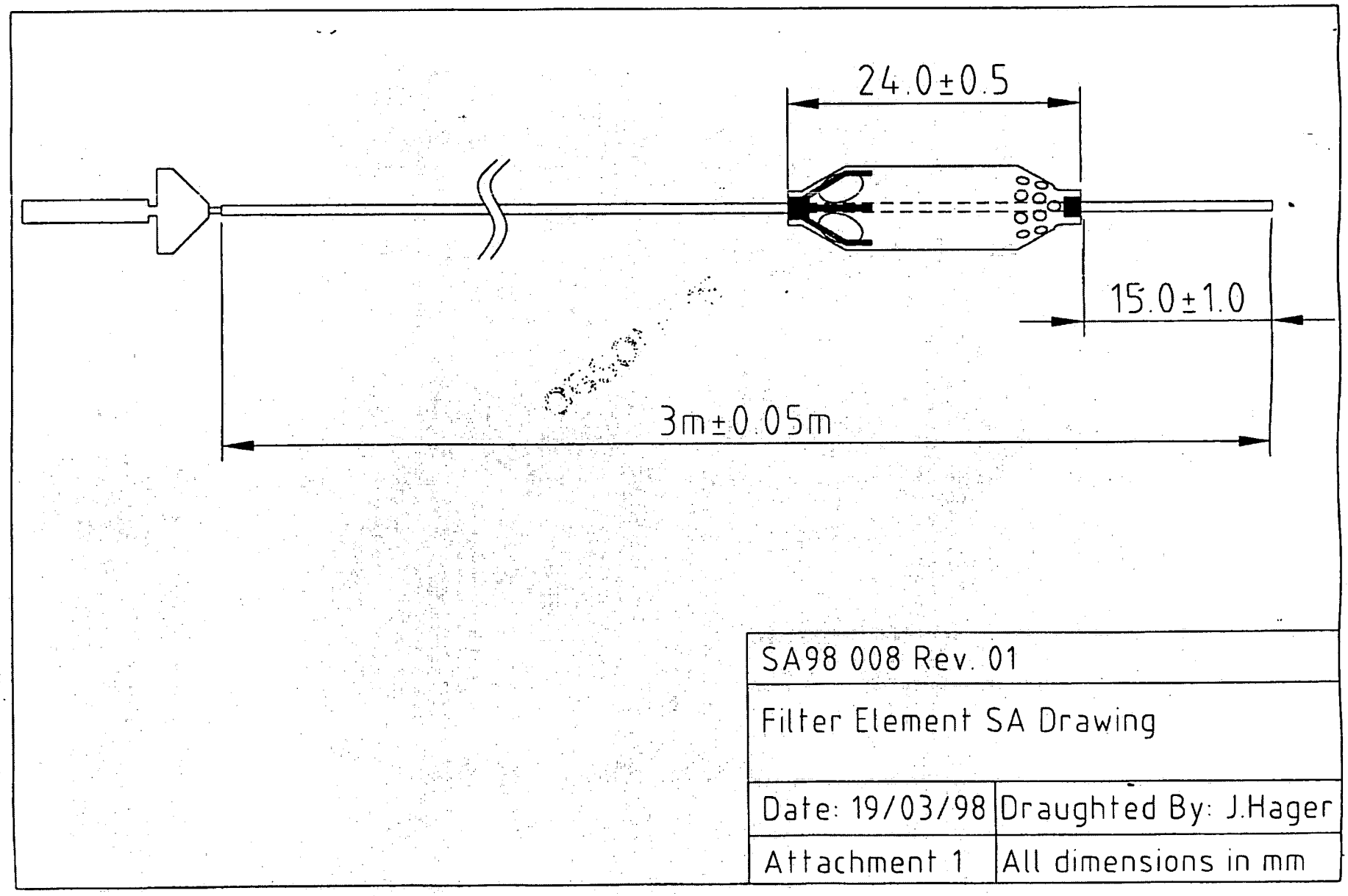
Comments:

Change Requested By

Print: Susan Eighan Sign: Susan Eighan Date: 24/4/98.

QA Engineer

Print: SHAUN O'ROURKE Sign: Shaun O'Rourke Date: 24/5/98



SA98 008 Rev. 01	
Filter Element SA Drawing	
Date: 19/03/98	Draughted By: J.Hager
Attachment 1	All dimensions in mm

Exhibit 55